

**EFFECT OF CITRIC ACID ON DIABETIC FOOT  
ULCER AMONG PATIENTS ADMITTED IN SELECTED  
WARDS OF SRI RAMAKRISHNA HOSPITAL,  
COIMBATORE.**

**REG. NO. 30101404**

A Dissertation submitted to  
**The Tamilnadu Dr. M.G.R. Medical University,**  
Chennai- 32

In partial fulfillment of the requirement for the  
Award of the Degree of

**MASTER OF SCIENCE IN NURSING**

**2012**

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COIMBATORE.**

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### **Abstract**

An interventional study was conducted to evaluate the effect of citric acid dressing for diabetic foot ulcers. One group pre test and post test with control group design was adopted. Using convenient sampling technique 16 patients with diabetic foot ulcer were selected in which 8 patients were in experimental group and 8 patients were in control group. Application of Citric acid was done for experimental group and routine dressing was done for control group for a period of 10 days and ongoing assessment was done to evaluate the wound status with Bates Jensen Wound Assessment Tool (2001). The data was analyzed with descriptive and inferential statistical methods. Mean, standard deviation, and 't' value of final wound status score of experimental and control group was calculated and the calculated 't' value (9.92) was greater than the table value significant at 0.05 level. The result shows that there is a significant improvement in the wound status after application of citric acid dressing when compared to the routine dressing for the diabetic foot ulcers. Hence the study concluded that application of citric acid was found to be effective measure in treating diabetic foot ulcers.

## **Effect of Citric Acid on Diabetic Foot Ulcer among Patients Admitted in Selected Wards of Sri Ramakrishna Hospital, Coimbatore.**

Diabetes mellitus is recognized as an epidemic in the Asian sub-continent affecting nearly more than 50 million in India alone. Diabetes is a disease of complication with decreasing life span for diabetic patients. The diabetic foot is one of the complications of diabetes and the end point is leg amputation that is most devastating for individual with diabetes.

The prevalence of diabetes mellitus is growing rapidly world wide. A study conducted by Sarah, Gojka, Andrews, Richard & Hilary (2009) on Global prevalence of Diabetes, shows that the prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and to be 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030.

As per the data given by International Diabetes Federation (Position statement-IDF, 2010), 366 million people are diabetics in 2011; by 2030 this will have risen to 552 million. The greatest number of people with diabetes is between 40 to 59 years of age.

In 2010, there were 45.2 million cases of type 2 diabetes mellitus in India. Of these, 14.7 million and 30.5 million were found in rural and urban areas, respectively. By the end of 2011, International Diabetes Federation (IDF) estimates that the total prevalent cases of type 2 diabetes will increase to 47.2 and 69.7 million in rural and urban areas respectively.

A study conducted in Tamilnadu State between the period 2009 and 2010 shows that 19 percentage of population are at a risk of diabetes mellitus. (Guptha, Sing, Purty, Kar & Maharajan, 2010) The Hindu reports that 48 lakh people in Tamilnadu have diabetics, with rural accounting for 7.8 per cent and urban 13.7 per cent. Around 2.8 lakh people have diabetes in Coimbatore district and 3.2 lakh people have pre-diabetes (Mohan, 2010).

People with diabetes are at risk of nerve damage (neuropathy) and problems with the blood supply to their feet (ischemia). Both neuropathy and ischemia can lead to foot ulcers and slow-healing wounds which, if they get infected, may result in amputation.

According to WHO 2010 studies, 25% of the patients develop diabetes related complications which are mostly due to poor diabetes control. The elevated blood sugar levels that occur with diabetes mellitus damage blood vessels causing them to thicken and cause poor blood circulation. These ulcers are slow to heal and often become deep and infected. Control of infection and healing of ulcers is difficult in diabetics due to compromised immunity, vasculopathy and neuropathy.

Diabetic foot is often quiet a dreaded disability, with long stretches of hospitalization, and impossible mounting expenses, with ever dangling end result of an amputated limb. The phantom limb plays its own cruel part on the already demoralized psyche.

Foot infection is the most common reason for hospitalization among diabetic patients accounting for up to 25% of admissions. Ulceration is more frequent in elderly population. Foot ulcerations and their sequelae remain a major morbidity for patients with diabetes mellitus often leading to infection. These infections have consistently ascertained as significant risk factors for lower extremity amputation. It is estimated that approximately 15% of the more than 150 million people with diabetes world-wide will at some stage develop diabetic foot ulceration (Boulton, Vilekeite & Ragnarson, 2009).

India is a home of 45 million diabetics, which is highest in the world out of which; nearly 15% suffers from the dreaded sequelae of diabetic foot. (Deresinki, 2008). If improperly or inadequately treated, these ulcers become infected or gangrenous and may ultimately lead to amputation of the affected limb. The annual rate of amputation varies from 41% to 77% per 10,000 patients with diabetes and accounts for nearly half of all the lower-limb amputations in hospitalized patients.

Diabetic foot ulcers are among the most devastating of all diabetic complications at a range of levels - social, physical, psychological and economic (Levin, 2002). People with active diabetic foot ulcers experience a reduction in quality of life (Pinzur, 2005).

New treatments for diabetic foot ulcer continued to be introduced. Recent development includes the use of bone marrow derived stem cells, negative pressure dressing, bioengineered skin equivalents and growth factor therapy, hyperbaric oxygen treatment, Maggot or larval therapy. Like wise various modalities are used to treat the diabetic foot ulcer. Moist wound healing is widely accepted concept.



Hydrocolloid dressing, enzymatic debridment agents, hydrogel dressings are some examples. Platelet derived growth factor and living skin equivalent products are the newest technological advancement in diabetic foot ulcer care. Though high tech treatments are available today the cost associated with these treatments are very high. The International Diabetes Federation stated that, in 2007, the world spent approximately US\$232 billion on the treatment and prevention of diabetes and its complications. This cost estimate is predicted to exceed US\$302.5 billion by 2025.

Citric acid treatment for diabetic foot ulcer is simple and effective approach. Citric acid shows promise as it causes a boost in fibroblastic growth and neovascularisation in wounds, aiding the formation of healthy granulation tissue which leads to faster healing and it is economic and affordable to all the population.

### **1.1. NEED FOR THE STUDY**

Diabetes mellitus is a common disease all over the world and its prevalence and incidence is steadily increasing. The availability of wide variety of treatment options result in improvement or even normalization of hyperglycemia as well as the accompanying complications. However people with diabetes continue to suffer from the complications of the disease. Foot ulceration is one of the most common formidable complications of diabetes.

Foot ulcers represent a severe complication of diabetes and are the most common cause of diabetes associated hospital admissions. (Sing, Amstong & Lipsky, 2005) In people with diabetes the prevalence of foot ulcers is 4–10%. Furthermore, the condition precedes 85% of major amputations. Approximately half of all foot

wounds become infected over the course of therapy. Compared with diabetic patients who do not have foot ulcers, those with diabetic foot ulcers have a 2.4-fold increased risk of death (Boyoko, Ahroni, Smith & Davignon, 1996).

Routine ulcer care, treatment of infections, amputations, and hospitalizations cost millions of rupees every year and place a tremendous burden on the health care system. In India it is estimated that diabetic foot problems is an expensive affair and an average individual spend about 50% of his income on diabetic problems (The Hindu, 2010).

Since the incidence of foot ulcers are increasing it is important to treat it to prevent from the development of any kind of complications. Small, superficial ulcers without significant contamination are often managed on an outpatient basis with frequent follow-up. More complex wounds with deep space infection and exposed bone, tendon or joint will necessitate hospital admission and a multidisciplinary team evaluation. A careful examination will be performed to determine the cause of the ulcer and appropriate treatment should be carried out.

The cornerstone of complex diabetic wound care is thorough surgical removal of unhealthy tissue (debridement). Devitalized skin, muscle and bone will be excised and deep tissue cultures sent to allow for optimization of antibiotic therapy. If debridement has resulted in exposure of important structures such as nerves, bones, tendons or joints then plastic surgical techniques may be required to close the wound. This may include local rearrangement of tissues (local flap), application of skin grafts or importing healthy tissue from a distant site utilizing microsurgical techniques (free flap). Infected diabetic foot wounds are complex problems that are optimally

managed by a multidisciplinary team. In the case of infection specialists customize antibiotic therapy and endocrinologists optimize control of blood sugar.

Living skin equivalent (LSE) products are the newest technological advances for diabetic foot ulcers. One LSE product consists of dermal fibroblasts cultured *in vitro* onto a bioabsorbable mesh to produce a metabolically active tissue that has histological characteristics similar to the dermal papillary of newborn skin.

Timely resolution of diabetic foot ulceration is essential if further tissue loss and infection are to be avoided. Current guidelines recommend the use of pressure relieving devices, appropriate dressings to promote healing and prevent infection, and where appropriate, debridement, drainage and revascularization (Hofman & Willie, 1994). In addition, optimization of glycaemic control and patient education are important factors in achieving successful ulcer healing (Lewis, Heitkemper & Dirksen, 2007).

Though we have high tech treatment and facilities these treatments are very costly and became unaffordable by the people of middle class society. Treatment with citric acid proves that it is simple, affordable and effective approach for the diabetic foot ulcers (Nagoba, 2008).

Citric acid treatment of chronic infected wounds offers excellent results. It has been found effective against a variety of bacteria causing wound infections. In vitro studies have revealed the efficacy of citric acid against bacteria resistant to multiple antibiotics. Citric acid shows promise as it causes a boost in fibroblastic growth and

neovascularisation in wounds, aiding the formation of healthy granulation tissue which leads to faster healing.

The high cost to treat the diabetic foot ulcers make it imperative to employ high tech and modern ways of treating it. But in the case of citric acid, it is relatively very low cost and reduces nearly 50 percentage of dressing costs. Clinical results with this treatment showed early formation of healthy granulation tissue and enhancement of the healing process, also it is simple, effective, reliable, non toxic and economic approach to treat the diabetic foot ulcers (Nagoba, 2010).

According to a study by Gandhi, (2010) citric acid has antibacterial activity as indicated by microbiological studies and by rapid clearing of infected surfaces. The reason for this antibacterial activity may be lowering of pH that makes an environment unfavorable for growth and multiplication of bacterial pathogens at infection site. Citric acid also enhances epithelization, which is a major factor in successful wound healing. Citric acid keeps the wound surface moist and prevents wound desiccation, thus reducing necrosis. Histological studies showed that it increases vascularity, which helps to remove dead tissue and makes the wound healthier. As a result of these actions, there is increased epithelial cell migration from surrounding skin, which enhances epithelization. In the present study citric acid was found to be nontoxic and active against a broad range of bacterial pathogens including those that were resistant to multiple antibiotics. Thus, it is highly effective and shares many characteristics and advantages of the ideal topical agent.

Considering the above facts the researcher decided to implement the citric acid dressing which is an effective and low cost measure to treat the diabetic foot ulcer.

## **1.2. STATEMENT OF THE PROBLEM**

EFFECT OF CITRIC ACID ON DIABETIC FOOT ULCER AMONG PATIENTS ADMITTED IN SELECTED WARDS OF SRI RAMAKRISHNA HOSPITAL AT COIMBATORE.

## **1.3. OBJECTIVES**

- 1.3.1. Assess the condition of foot ulcer among patients with diabetes mellitus.
- 1.3.2. Application of citric acid dressing on foot ulcer among patients with diabetes mellitus.
- 1.3.3. Evaluate the effectiveness of citric acid on diabetic foot ulcer.

## **1.4. OPERATIONAL DEFINITIONS**

### **1.4.1. Diabetic Wound**

Refers to the disruption in continuity of skin. It refers to partial thickness wound among diabetic patients admitted in Sri Ramakrishna Hospital as assessed by Bates Jensen Wound Assessment Tool.

### **1.4.2. Diabetic Patient**

Refers to patients who are diagnosed as type I and II diabetes mellitus admitted to Sri Ramakrishna hospital, Coimbatore.

### **1.4.3. Wound Status**

It refers to the condition of the diabetic wound in terms of wound size, presence of infection, depth of wound, presence of necrotic tissue, type and amount of

exudates, wound edges, and granulation tissues, measured by using Bates Jensen Wound Assessment Tool.

#### **1.4.4. Wound Healing**

In this study wound healing refers to formation of granulation tissues and measured in terms of reduction in wound assessment score.

#### **1.4.5. Effect**

It refers to the change in wound status brought about by citric acid dressing and also measured in terms of time taken for healing and cost of treatment.

#### **1.4.6. Application of Citric Acid**

It refers to the process of application of 20 to 30 ml of citric acid absorbent dressing on diabetic wound once daily.

#### **1.4.7. Citric Acid**

It refers to the 3% citric acid crystals (Citric acid anhydrous) solution which prepared from dissolving 3 grams of citric acid crystals in 100 ml of sterile water.

### **1.5. CONCEPTUAL FRAME WORK**

Conceptualization refers to the process of developing and refining abstract ideas (Polit & Beck, 2008). Conceptual model provide a conceptual perspective regarding inter selected phenomenon. A conceptual model broadly presents an understanding of the phenomenon of interest and reflects the assumption and philosophical views.

The conceptual framework adopted for the present study is based on Lydia Hall's Core, Care, Cure Model. Hall's theory which has 3 major tenets. Nursing functions are presented in three different interlocking circles constituting different aspects of the patient. These three circles represent the patient's body, the disease affecting the body and the nursing care provided. Nursing operates in all three circles in appropriate role.

#### **1.5.1. The Core Circle**

The core is the patient care which involves the therapeutic use of self and shared with other members of the health team. The motivation and energy necessary for healing exists with the patient rather than the health care team. In this study the core part of the system are the factors which influence the wound healing. In order to identify these factors demographic & physiologic variable proforma was used and Bates Jensen's wound assessment scale was used to assess the wound healing process.

#### **1.5.2. The Care Circle**

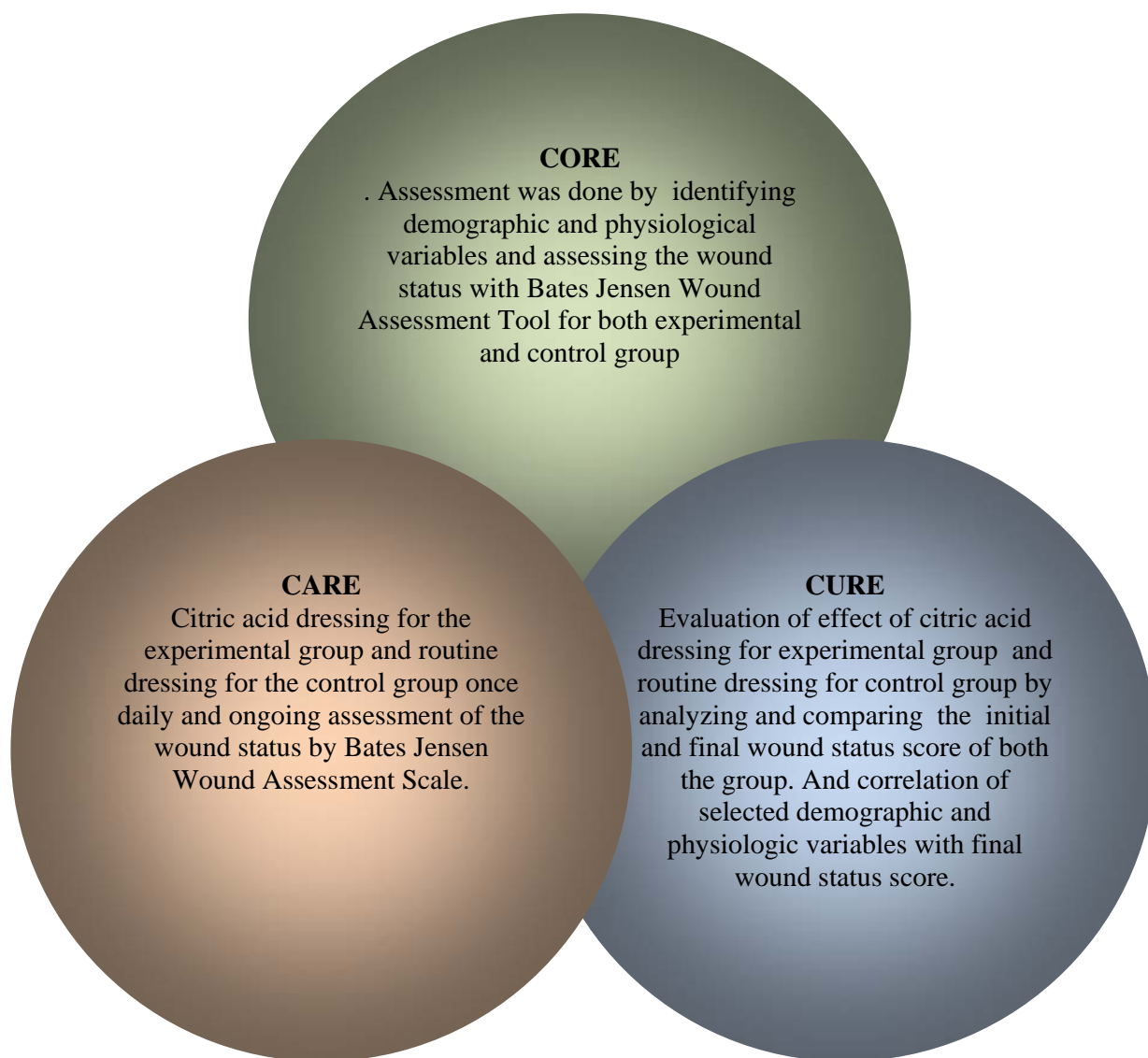
The care represents the nurturing component of nursing and is exclusive to nursing. When functioning in the care circle, the nurse applies knowledge of natural and biological sciences to provide strong theoretical base for nursing actions. The patients in experimental group received citric acid dressing and routine dressing was applied in the patients of control group. An on going assessment was done to find the healing process of the foot ulcer.

### **1.5.3. The Cure Circle**

The cure part determines the process of wound healing. It represents the outcome of the care being rendered. Wound assessment scale was used to assess the condition of the wound. The cure circle include the evaluation of wound status by daily on going assessment of wound status in terms of change in wound size, depth, necrotic tissue, edges, exudates amount and type, and development of granulation tissue of both experimental and control group patients. Comparison of final wound status score of experimental and control group was done to assess the effect of citric acid dressing.



**FIG 1.1**  
**CONCEPTUAL FRAMEWORK BASED ON**  
**LYDIA HALLS CORE, CARE, CURE MODEL**



(Kim & Kollak, 2006)

## **1.6. PROJECTED OUTCOME**

The application of citric acid dressing on diabetic foot ulcer will help to improve the wound healing process when compared to the routine wound dressing.

## **REVIEW OF LITERATURE**

Diabetes mellitus is a multisystem disease related to abnormal insulin production, impaired insulin utilization or both. Diabetes mellitus is a serious health problem throughout the world. Diabetes is the leading cause of heart disease, stroke, adult blindness, foot ulcers and non traumatic lower limb amputations.

The present study aims at bringing about the effectiveness of application of citric acid on diabetic wound healing.

The review of literature has been done under the following headings:

- 2.1. Literature related to diabetes mellitus, diabetic foot ulcer and its treatment
- 2.2. Literature related to treatment with citric acid
- 2.3. Literature related to application of citric acid for wound healing.

### **2.1. LITERATURE RELATED TO DIABETES MELLITUS, DIABETIC FOOT ULCER AND ITS TREATMENT**

#### **2.1.1. Diabetes Mellitus**

Diabetes is a disorder of metabolism and of the circulation. Chronic metabolic irregularities linked to poor circulatory perfusion and nerve damage can affect a number of organ systems, including skin tissues.

Diabetes mellitus is classified into type I and type II. Type I diabetes is most commonly diagnosed in children and adolescent, but can occur in adults as well. It is an auto immune disorder. Other pancreatic problems including trauma or tumor can

also lead to the loss of insulin production and this is treated with insulin injections, life style adjustments careful monitoring of glucose levels.

According to Guptha, Sing, Purty, Kar & Maharajan (2010) Type 2 Diabetes Mellitus (T2DM) is a non-autoimmune, complex, heterogeneous and polygenic metabolic disease condition in which the body fails to produce enough insulin, characterized by abnormal glucose homeostasis. Its pathogenesis appears to involve complex interactions between genetic and environmental factors. T2DM occurs when impaired insulin effectiveness (insulin resistance) is accompanied by the failure to produce sufficient insulin.

According to Chandiala (2001) Diabetes mellitus basically produces changes in the blood vessels and hence can affect almost every part of the body. Long standing diabetes mellitus is associated with an increased prevalence of micro-vascular and macro-vascular diseases. The onset of Type 2 diabetes is usually insidious and the patient may remain asymptomatic until late stages of the disease. The prevalence of peripheral vascular disease (PVD) among Indians is 4-6% which is comparatively lower as compared to 9.3% among the white population. Diabetic foot is a common cause of hospital admissions among diabetics in India. Diabetic neuropathy is also common and an additional risk factor for foot infections.

According to Vinik (1999) about 60% to 70% of patients with diabetes have some degree of neuropathy, with neurologic complications occurring equally in type I and type II diabetes. The most common type of neuropathy affecting persons with diabetes is sensory neuropathy. This can lead to the loss of protective sensation in the

lower extremities and coupled with other factors, this significantly increase the risk of complications that result in foot ulcers.

Vishwanathan & Kumpatla (2011) conducted a study to assess the pattern and causes of amputations in diabetic patients across various parts of India. A total of 1985 type 2 diabetic subjects were selected from 31 centres across India. Out of 1985 subjects, a total of 1295 patients who had undergone amputations both major and minor were included in this analysis. The major cause for the occurrence of amputations among the patients was found to be infection. Almost 90% of the patients had infection. Patients had different types of amputations: major amputations accounting for 29.1% (n=377) and minor amputations in 70.9% (n=918) of subjects. Among the subjects who underwent major amputations, more than 50% accounts for below knee amputations and 11.9% above knee amputations. Out of total amputations, over half of the amputations were of toes. Presence of claw toes was seen in 64% of patients. Prevalence of neuropathy (82%) was high and 35% had peripheral vascular disease. The study concluded that, foot infection was found to be the major cause of amputation in India.

Mani, Yarde, & Edmonds (2011) reports the result of prevalence of venous incompetence, impaired calf vein hemodynamic, and loss of micro vascular control in the skin over the dorsum of the foot in an effort to document whether increased retrograde pressure caused due to venous incompetence or loss of sympathetic regulation of the microcirculation is present in the diabetic patient who is at risk of foot disease. It was found that 64% and 70.7% of diabetic patients had deep venous incompetence in their right and left legs, respectively, which was statistically

significantly greater than what was found in a previous report on the general population ( $P < .05$ ); 42.7% and 49.3% of patients had a reduced venous refilling time in the right and left legs, respectively, and 30.7% and 33.3% of patients had loss of the arteriovenous response in the right and left legs. The outstanding contribution of this report is the finding of venous incompetence in patients with diabetes results in diabetic foot disease.

A study was conducted by Srivijitkamol, Mounngern & Vannaseang (2011) to determine factor(s) associated with reduced assessment of diabetic complication and to determine the prevalence of diabetic complications in type 2 diabetes patients. The researcher conducted a retrospective review of medical records of type 2 diabetes patients who were followed up at the out-patient department (OPD) of Department of Internal Medicine at Siriraj Hospital Mahidol University Thailand during 1st January to 31st December 2006. Of 722 diabetes patients who were recruited. On which the prevalence of diabetic nephropathy and chronic kidney disease of at least stage 3 were 37 and 48.2%, respectively. Diabetic retinopathy occurred in 31.2%, cardiovascular disease in 28.9%, cerebrovascular disease in 10.6% and diabetic foot in 40%. There was a high prevalence rate of diabetic complications in patients with type 2 diabetes. Screening for diabetic complications will help to identify patients at high risk of concomitant complications even though some practitioners are not initially aware of the importance of the diabetic complication screening. These data may help the physician decide to modify treatment to prevent disabilities.

### **2.1.2. Diabetic Foot Ulcer**

Zubair, Malik & Ahmad (2011) conducted a study in North India to evaluate the incidence and risk factors for amputation among patients with diabetic foot ulcer (DFU). A prospective study of 162 DFU in patients treated in a multidisciplinary based diabetes and endocrinology centre of Jawaharlal Nehru Medical College of Aligarh Muslim University, India during the period of December 2008-March 2011. Detailed history and physical examination was carried out for every subject. Risk factors for amputation were determined by univariate analysis with 95% of CI. The overall amputation rate was 28.4%. The risk factors identified for amputation were presence of PVD, leukocytosis, neuropathy, nephropathy, hypertension, dyslipidemia, over use of antibiotics, osteomyelitis, bio film production and higher grade of ulcer.

Shankhadar (2009) conducted a study in which the researchers assessed 300 diabetic people and 100 age- and sex-matched controls for correlating foot wear practices and foot care knowledge and the presence of foot complications. A structured questionnaire evaluated the knowledge about foot care, type of footwear used, education level, association of tobacco abuse, and any associated symptoms of foot disease. Clinical evaluation was done by inspection of feet for presence of any external deformities, assessment of sensory function (vibration perception threshold, VPT), vascular status (foot pulses and ankle brachial ratio) and presence of any infection. Fourteen (4.7%) patients gave history of foot ulceration in the past and comprised the high risk group; only 2 out of 14 had received foot care education, 6 gave history of tobacco abuse, 8 had symptoms of claudication, 9 had paresthesias, 2 walked barefoot indoors. Average duration of diabetes in the high-risk and low-risk diabetes group was 10.85 and 9.83 years, respectively. In the high- and low-risk

diabetic groups, VPT was 11.26 and 10.21V ( $P < 0.02$ ). The study shows, poor knowledge of foot care and poor footwear practices were important risk factors for foot problems in diabetes.

A prospective study was carried out by Bansal & Garg (2008) on patients with diabetic foot lesions to determine their clinical characteristics, the spectrum of aerobic microbial flora and to assess their comparative in vitro susceptibility to the commonly used antibiotics. A total of 157 organisms (143 bacteria and 14 fungi) were isolated and an average of 1.52 isolates per case was reported. Polymicrobial infection was found in 35% of the patients. In this study, *Pseudomonas aeruginosa* among the gram-negative (22%) and *Staphylococcus aureus* among the gram-positive (19%) were the predominantly isolated organisms, while *Candida* was the most predominantly isolated fungus. Neuropathy (76%) and peripheral vascular disease (57.28%) was a common feature among the patients. Poor glycemic control was found in 67% of the patients. Awareness about lower limb complications of diabetes was very low (23%) among the patients.

### **2.1.3. Treatment of Diabetic Foot Ulcers**

An article by Aggarwal (2004) states that successful treatment of diabetic ulcers relies on reducing or eliminating, resolving infection, correcting ischemia and maintaining an environment that promotes wound healing.

Nain, Uppal, Bajaj & Garg (2011) conducted a study to compare the rate of ulcer healing with the negative pressure dressing technique to conventional moist dressings in the treatment of diabetic foot ulcers. The study was conducted on 30 patients, which were divided into two groups. One group received negative pressure



dressing while other group received conventional saline moistened gauze dressing. Results were compared for rate of wound healing. There was a statistically significant difference in the rate of appearance of granulation tissue between the two groups; with granulation tissue appearing earlier in the study group. The study group promised a better outcome (80% complete responders) as compared to the control group (60% complete responders). Negative pressure wound therapy has a definitive role in healing of diabetic foot ulcers.

Dumville & Deshpande (2011) conducted randomised controlled trials (RCTs) that have compared the effects on ulcer healing with hydrogel with alternative wound dressings or no dressing in the treatment of foot ulcers in people with diabetes. The study included 446 participants and the result shows that hydrogel dressings are more effective in healing lower grade diabetic foot ulcers than the basic wound contact dressings.

Tiaka, Papanas & Manolakis (2008) investigated the use of Hyperbaric oxygen (HBO) in addition to standard treatment of the diabetic foot for more than 20 years. Evidence suggests that Hyperbaric oxygen reduces amputation rates and increases the likelihood of healing in infected diabetic foot ulcers, in association with improved tissue oxygenation, resulting in better quality of life. Nonetheless, Hyperbaric oxygen represents an expensive modality, which is only available in few centers. The study shows that, Hyperbaric oxygen appears promising, but more experience is needed before its broad implementation in the routine care of the diabetic foot.

Nather (2010) conducted a prospective study to determine the effectiveness of vacuum-assisted closure (VAC) therapy in the healing of chronic diabetic foot ulcers. An electronic vacuum pump was used to apply controlled negative pressure evenly across the wound surface. Changes in wound dimension, presence of wound granulation and infection status of diabetic foot ulcers in 11 consecutive patients with diabetes were followed over the course of VAC therapy. Healing was achieved in all wounds. The average length of treatment with VAC therapy was 23.3 days. Ten wounds showed reduction in wound size. All wounds were satisfactorily granulated and cleared of bacterial infection at the end of VAC therapy. VAC therapy also provides a sterile, more controlled resting environment to large, exudating wound surfaces. Large diabetic foot ulcers were thus made more manageable.

Gottrup & Jorgensen (2011) described the efficacy of Maggot debridement therapy (MDT) for treating wound especially diabetic foot ulcers. Literature and the results demonstrate that Maggot debridement therapy is a safe method with few side effects. Maggot debridement therapy is as good as or better than conventional often surgical debridement, is more selective than surgical debridement, because it decreases time to healing and stays of patients in the ward, and may decrease the risk of major amputations.

Culleton (1999) said improving glucose control and educating patients in routine care of their feet can reduce the incidence of diabetic foot complication. A foot lesion should be assessed for infection, radiographically for foreign body, soft tissue and bony abnormalities. Under estimating the severity of a foot lesions can lead to prolonged morbidity and possibility of unnecessary amputation. Tight glucose

control can reduce micro vascular diabetic complication including peripheral sensory neuropathy and thus development of diabetic foot ulcers.

Fujiwara, et al., (2011) conducted a study to assess the effectiveness of a preventative foot care nursing programme for diabetic patients. The researchers developed a diabetic foot care programme based on the International Working Group on the Diabetic Foot and studied 88 patients who attended foot care programme for 2 years, and collected data from April 2005 to March 2009. Patients were divided into four groups according to the risk classification, and received foot care and evaluated the incidence of foot ulceration or recurrence and non-ulcerated foot condition. The programme reduced the severity score of tinea pedis ( $P < 0.001$ ) and improved callus grade ( $P < 0.001$ ). The researchers found that nurse-based foot care programme is effective in preventing diabetic foot in diabetic patients.

## **2.2. LITERATURE RELATED TO TREATMENT WITH CITRIC ACID**

Femiano, Rulla & Lanza (2010) conducted a study aiming to compare the efficacy of saliva substitutes and citric acid long-term therapy for oral dryness relief and unstimulated salivary flow in patients reporting drug-induced xerostomia. Fifty-four patients reporting drug-induced xerostomia were randomly subdivided into 3 groups and respectively administered artificial saliva, 3% citric acid, or distilled water in mouthwash 4 times a day for 30 days. The result shows that citric acid provided immediate relief from oral dryness. Citric acid provided a longer-lasting feeling of oral moistness at 1 hour after use owing to its protracted activity on salivary gland function.

Zazgornik (2011) conducted a study to find the eradication property of citric acid. The researcher finds that citric acid inhibits the growth of *Helicobacter pylori* in vitro. About 50% of the world population is infected with *Helicobacter pylori*. The inhibitory effect of 3% hydrogen peroxide, 8.4% sodium bicarbonate, 2% ascorbic acid, citric acid in combination with sodium citrate, 7% and 14% citric acid solutions, respectively, on nine *Helicobacter pylori* strains were tested in vitro. Citric acid showed a 92% of potent inhibitory activity on growth of *Helicobacter pylori* strains in vitro than the other compounds which were used. Citric acid is a cheap substance present in many fruits and produced by food industry and it demonstrated powerful inhibitory effect on the growth of *Helicobacter pylori* strains.

Renvert, Dahlen & Snyder (1997) conducted a study in Sweden to compare an enzyme immunoassay with culture samples from untreated and non-surgically treated periodontal pockets and to assess the clinical and microbiological effects of citric acid irrigation as a supplement to scaling and root planning. The enzyme immunoassay used in this study is a chair side diagnostic tool aimed at identifying the presence of *Pseudomonas gingivalis*, *intermedia*, and *actinomycetemcomitans*. Six sites with pocket depths  $\geq 6$  mm in each of 16 patients were monitored for 24 weeks using clinical and microbiological parameters. In two out of the six sites, scaling and root planning was supplemented with sub gingival citric acid irrigation of the pocket after completion of the mechanical treatment. The sensitivity of the immunoassay in relation to culture was calculated to 85.5% and the specificity to 90.2%. The immunoassay corresponded to a detection level of  $10^4$  as estimated by culture. Sites treated with a combination of scaling and irrigation with citric acid demonstrated a similar healing pattern as sites treated with scaling and root planning alone. The

results of this investigation thus indicated that adjunctive irrigation with citric acid has measurable clinical and microbiological effects.

Davidson & Haslett (2002) described ascorbic acid essential for activating the enzyme prolylhydroxylase which promotes the hydroxylation step in the hydroxyproline an integral constituent of collagen. Without ascorbic acid collagen formed is defective and weak. This vitamin is essential for growth of subcutaneous tissue, cartilage, bone, teeth. Scurvy is failure of wound to heal. This is caused by failure of the cells to deposit collagen fibrils and intramuscular cement substance.

Weller (2006) conducted systematic review and randomized control trials on the effects of application of a nitric oxide generating acidified nitrite cream comprising sodium nitrite and citric acid, on the healing of incisional wounds. The effects of acidified nitrite on wound healing were critically dependent on the time of application after wounding. Application of acidified nitrite starting on the day of wounding and on consecutive days thereafter significantly inhibited both half time to closure and extent of wound closure. Conversely, application starting on days 1-4 after wounding and on consecutive days thereafter significantly augmented the rate and extent of wound healing. Optimal effects on improving wound healing were observed with cream concentrations of 3.0% (w/v) sodium nitrite and 4.5% (w/v) citric acid. Starting application on day 5 after wounding had no effect on the rate or extent of wound healing. Acidified nitrite at 3.0% (w/v) sodium nitrite and 4.5% (w/v) citric acid significantly increased the rate and extent of wound healing. This suggests that acidified nitrite is effective in improving wound healing. The present data shows that a clinically effective means of topically delivering citric acid augments the wound healing process and may be of clinical benefit.

### **2.3. LITERATURE RELATED TO APPLICATION OF CITRIC ACID FOR WOUND HEALING**

Nagoba (2007) conducted a study to prove the effect of Citric acid treatment for postoperative wound healing in MIMSR medical college, Maharashtra. A 40-year-old female presented with history of swelling at the upper and middle of the left leg since 6 months was confirmed as post cancer surgery non healing wound not responding to conventional antibiotic therapy and local wound care in an operated case of synovial sarcoma of the knee, monophasic fibrous type with no lung metastasis. Post surgical non healing wound not responding to conventional therapy was treated successfully with local application of 3% citric acid ointment for 25 days. And the researcher found that treating post surgical wounds with 3% citric acid is a useful measure in the clinical areas.

Lickman, Fontento & Rahnema (1995) conducted randomized clinical approach for 32 patients and used citric acid and hyaluronic acid based gel dressing done for diabetic foot ulcer and found that this dressing provides a moist healing environment, rapidly clears infection, deodorizers and reduces inflammation, edema and exudation. Also the results show the healing rate of wound is increased by the stimulation of angiogenesis, granulation and epithelization.

Nagoba, et al., (2008) conducted a study to develop an approach, using citric acid as a sole antimicrobial agent, for the treatment of chronic wound infections caused by multiresistant *Escherichia coli* (MAREC). A total of 34 cases of chronic wound infections yielding MAREC isolates on culture were studied. The antibacterial effect of citric acid against MAREC was evaluated in vitro by broth dilution method.

Three percent citric acid gel was applied to each wound once daily until it healed completely. All 34 isolates were inhibited by citric acid with minimum inhibitory concentrations in the range of 1500-2000 microg/ml. Topical application of 3% citric acid to wounds 7-42 times resulted in elimination of MAREC from infected sites and successful healing of wounds in all 34 patients. This treatment modality was simple, reliable, non-toxic and effective. Hence, the use of citric acid for the cost-effective treatment of wound infections caused by MAREC is recommended.

According to Hess (2005) in tissue repair vitamin C directly affects the normal production and maintenance of matrix materials especially collagen. Vitamin C also strengthens and promotes the formation of new blood vessels. With vitamin C deficiency even superficial wounds fail to heal and the walls of the blood vessels become fragile and are easily ruptured.

Gandhi (2010) conducted a study to develop a simple and effective treatment modality using citric acid as a sole antimicrobial agent to control infections in burns patients not responding to conventional treatment. Forty-six cases with 5-60% superficial to deep burns in a study group and 20 cases with 10-70% superficial to deep burns in a control group were investigated for culture and susceptibility. The isolates in study group were further tested for susceptibility to citric acid. Three percent citric acid gel was applied to burns wounds in study group; however, the control group received conventional antibiotic therapy and local wound care. In the control group. Application of citric acid to burn wounds resulted in complete healing in 40 (86.95%) cases in 7-25 applications (P value 0.145); however, in a control group conventional antibiotic therapy and local wound care resulted in complete healing in

nine (45%) patients only. Citric acid treatment was found effective in the control of burns infections as compared to conventional therapy. Complete healing in 86.95% cases as compared to 45% in a control group indicates that citric acid is nontoxic, economical and quite effective in the management of burns infections.

Wadher, Kore, Gomashe & Ingle, (2008) conducted a study to develop simple and effective treatment modality by using citric acid a sole antimicrobial agent to control diabetic foot infections not responding to conventional treatment. 115 cases of diabetic foot ulcers of different Wagner grades infected with a variety of bacteria were investigated for culture and susceptibility, and susceptibility to citric acid. Citric acid gel was applied to ulcer to determine its efficacy in the management of diabetic foot ulcers. Citric acid gel was found effective in the control of foot infections, and the success rate was more than 94%.

Van, Halker, Ufford & Hoekstra (2003) conducted randomized clinical trials on diabetic foot ulcer patients and found that a novel formulation of metal ions and citric acid reduces reactive oxygen species in vitro which plays an important role in wound healing. Reactive oxygen species react with nitric oxide produced by macrophages to form peroxynitrate, another strong oxidant with detrimental effects on surrounding tissue. This study investigated whether samples of metal ions and citric acid are able to reduce levels of reactive oxygen species. Samples of materials were tested in assays by checking inhibition of reactive oxygen species production by polymorphonuclear neutrophils (PMN), antioxidant activity and inhibition of human complement. The result shows that the citric acid was found to cause significant reduction of super oxide thus promoted wound healing.



Allen (2008) did an extensive study to evaluate the efficacy of citric acid application in the treatment of wound healing. Literature review was carried out from July 2000 to July 2008. The 5 observational studies with 165 patients and 245 cases in 10 controlled trials where 42 patients were treated with citric acid. Most of the patients reported 95% of complete wound healing within 3- 8 weeks in observational and 62% in controlled trails.

According to a clinical trail conducted by Ormerod & Shah (2008). At University of Wisconsin School of medicine and public health, identify the low cost effectiveness of citric acid based dressing for treating diabetic ulcers. The experimental group receives citric acid based gauze dressings on the diabetic wound for a duration of 1 month. At the end of second week granulation tissues appeared at a period of 2 to 4 weeks the ulcers resolved completely. It shows citric acid based dressing has excellent track on wound healing.

Gutyon (2009) included 104 cases of superficial burn injury to assess the efficiency of citric acid as a dressing in comparison with silver sulfadiazine gauze dressing. In 52 patients treated with citric acid and the 91 percent of wounds were rendered sterile within 7 days. In 52 patients treated with silver sulfadiazine, 7% showed control of infection within 7 days. Healthy granulation tissue was observed earlier in patients treated with citric acid (mean 7.4 versus 13.4 days). In control group only 10% of wounds healed within 15 days. It shows citric acid as an ideal dressing in the treatment of wound healing.

## **METHODOLOGY**

This chapter designs the research methodology employed in the present study. It encompasses the following topics in detail. They are research approach, research design, setting, population, sampling, variables of the study, materials for data collection, validity of the tool, hypothesis and technique for data analysis and interpretation.

### **3.1. RESEARCH APPROACH**

Quantitative research approach was adopted for the study.

### **3.2. RESEARCH DESIGN**

One group pre test and post test with control group design was adopted to find the effectiveness of citric acid dressing in the healing of diabetic foot ulcer.

### **3.3. SETTING**

The study was conducted in the surgical ward and special wards of Sri Ramakrishna Hospital, Coimbatore, Tamilnadu. Surgical ward consists of 54 beds. Clients affected with diabetic foot are treated in the surgical wards and special wards of Sri Ramakrishna Hospital.

### **3.4. POPULATION**

The population for the present study was patients with diabetic foot ulcer admitted in Sri Ramakrishna Hospital.

### **3.5. CRITERIA FOR SELECTION OF SAMPLES**

#### **3.5.1. Inclusion Criteria**

Patients with type I and type II diabetes mellitus who are admitted with diabetic wound/ diabetic foot ulcer.

#### **3.5.2. Exclusion Criteria**

- i. Clients who are critically ill
- ii. Clients who are on treatment with corticosteroids, radiation therapy and immunosuppressive drugs.
- iii. Clients with protein energy malnutrition as diagnosed by physician.

### **3.6. SAMPLING**

A convenient sample of 16 participants with diabetic foot ulcer, both male and female were drawn as samples for the present study and randomly assigned to the experimental and control group respectively.

### **3.7. VARIABLES OF THE STUDY**

#### **3.7.1. Independent Variable**

Local application of citric acid

#### **3.7.2. Dependent variable**

Status of the diabetic foot ulcer and level of wound healing as measured on Bates Jensen Wound Assessment Tool.

#### **3.7.3. Extraneous variables**

The extraneous variables were antibiotics and dietary pattern of the patients.

### 3.8. MATERIALS

#### 3.8.1. Demographic & physiologic variable Profoma

#### 3.8.2. Bates Jensen Wound Assessment Scale (2001)

**3.8.1. Demographic & Physiologic Variable Profoma** : Demographic & physiologic data was collected from the patients and hospital records which include age, gender, and history of smoking, duration of diabetes mellitus, history of foot ulcer, fasting blood sugar and hemoglobin levels, medication, dietary pattern, exercise.

**3.8.2. Bates Jensen Wound Assessment Tool (2001)**: Bates Jensen Wound Assessment Tool is a standardized tool developed in the year 1995 by Barbara Bates Jensen and revised in 2001. The Bates Jensen wound assessment tool contains 13 characteristics which assess the wound status. These characteristics included location and shape of the wound, size in centimeters square, depth, appearance of edges, undermining or tunneling, necrotic tissue type and amount, exudate type and amount, surrounding skin condition, peripheral tissue edema and induration, granulation tissue appearance and epithelialization (Bates-Jensen & MuNees, 2001)

#### Scoring and Interpretation of the Bates Jensen Wound Assessment Tool (2001) :

In the BWAT, 13 characteristics of wound status are scored using a Likert-type scale; a score of **1** - indicates the healthy wound and **5** - indicates the most unhealthy wound attribute for each characteristics. Item sub scores are added to obtain a total score. The scores range from 13-65 with the higher number demonstrating a worse condition of the wound.

The Bates Jensen wound assessment scale (2001) has internal consistency and reliability obtained for this tool is 0.91 and yielded high correlation.

### **Administration of the Tool**

Bates Jensen wound Assessment tool consists of 13 items which are administered by following the specific instructions and the scoring is entered on the assessment format with date and the scores are plotted on the wound status continuum.

1. Size: a sterile metric scale was used to measure the longest and widest aspect of the wound surface.
2. Depth: depth is identified by the most appropriate wound description of the following and 1 to 5 scores are given respectively
  - (i) Tissues damaged but no break in skin
  - (ii) Superficial, abrasion, blister, or shallow crater.
  - (iii) Deep crater with or without undermining of adjacent tissue
  - (iv) Visualization of the wound is obscured by necrosis
  - (v) Supporting structures include tendon, joint capsule are also involved.
3. Edges : edges of the wound is identified and scored by the following guideline:
 

Indistinct	=	wound outline is unable to clearly distinguish.
Attached	=	flat or even wound base
Not attached	=	base of the wound is deeper than the edge
Rolled under, thickened	=	soft to firm and flexible to touch
Hyperkeratosis	=	callous like tissue formation around wound and at edges.

Fibrotic, scarred = hard to touch

4. Undermining: undermining refers to the deep tissue damage around the wound margin, and it is assessed by inserting cotton tipped applicator at the wound edges and scored as per the guideline in the tool.
5. Necrotic tissue type: necrotic tissue of the wound is identified according to colour, consistency and adherence.
6. Necrotic tissue amount: transparent metric measuring scale with concentric circles divided into 4 (25%) pie shaped quadrants to determine percent of wound involved.
7. Exudates type: whether the exudate is bloody, serosanguineous, serous, purulent, foul or foul purulent is assessed.
8. Exudates amount: a transparent metric measuring scale with concentric circles divided into 4 (25%) pie- shaped quadrants is used to determine the exudates amount. And according to the percentage it is determined that the amount of exudates is scant, small, moderate, or large.
9. Skin colour surrounding wound: the colour of the tissues with in 4 cm of wound edge is assessed.
10. Peripheral tissue edema: the edema of the peripheral tissue is assessed with in 4 cm of wound edge. Non pitting edema appears as skin that is shiny and taut. Pitting edema is identified by firmly pressing a finger down in to the tissues and waiting for 5 seconds, on release of pressure, tissues fails to resume previous position and indentation appears. A metric scale is used to find how far the edema is spread to the surroundings.

11. Peripheral tissue induration: it is assessed by gently pinching the tissues. Induration results in an inability to pinch the tissues. A metric scale is used to find how far the induration is spread.
12. Granulation tissue: it is identified by visualising the wound. When the tissue is bright, beefy red, shiny, and granular with a velvety appearance it is said to be healthy. Poor tissue health appears as pale pink or blanched to dull, dusky red colour.
13. Epithelialisation: a transparent metric measuring scale with concentric circles divided into 4 (25%) pie shaped quadrants to determine percentage of wound involved.

The scores obtained are interpreted as; increase in the wound status score indicates the wound degeneration and poor wound healing. Decrease in the wound status score indicates the wound regeneration and tissue healing.

### **Preparation of citric acid solution**

3% Citric acid solution is prepared by adding 3 grams of citric acid crystals in 100 ml of sterile water. The prepared solution is used for dressing not more than 7 days (Nagoba, 2008).

### **Wound dressing**

Diabetic foot dressing was done as per protocol which was prepared by the researcher with literature review and expert guidance (Appendices-VI).

### **3.9. HYPOTHESIS**

H<sub>01</sub>: There is no significant difference in the wound status among experimental and control group before the application of citric acid.

H<sub>2</sub> : There is a significant difference in wound status among experimental group before and after the application of citric acid .

H<sub>3</sub> : There is a significant difference in wound status among control group before and after routine wound dressing.

H<sub>4</sub> : There is a significant difference in wound status among experimental and control group after application of citric acid.

### **3.10. PILOT STUDY**

Pilot study was conducted to find out the feasibility and practicability of the study. The study was conducted in Sri Ramakrishna hospital for a period of ten days. Convenient sample of 6 diabetic foot ulcer patients were selected, three were assigned to experimental group and three assigned to control group randomly. Bates Jensen wound assessment scale was used to assess the wound status. Assessment was done every day before each dressing. The result revealed that there is a significant improvement in the status of wound after the application of citric acid dressing.

### **3.11. MAIN STUDY**

The main study was conducted to meet the objectives of the present study. The data was collected for a period of 30 at Sri Ramakrishna Hospital. Using convenient sampling technique 16 patients were selected in which 8 patients were in experimental group and 8 patients were in control group. The baseline data were obtained from the patients and hospital records of the patients. The researcher collected the data by the following technique:

1. Selection of samples with diabetic foot ulcer
2. Collection of demographic data and physiologic variables



3. Assessment of the wound status with Bates Jensen Wound Assessment Tool
4. Application of citric acid dressing for experimental group and routine dressing for control group once per day.
5. Assessment of the final wound status score on the 10<sup>th</sup> day of treatment.

### **3.12. TECHNIQUE OF DATA ANALYSIS & INTERPRETATION**

Appropriate statistical technique such as descriptive statistics was used to analyze demographic and physiologic variables. Inferential statistics ('t' test) was used to assess the significance in wound status score in experimental and control group and to assess the effect of citric acid dressing. Karl Pearson's correlation coefficient was used to find the relationship between the selected demographic & physiologic variables with final wound status scores.

## **DATA ANALYSIS AND INTERPRETATION**

This chapter represents the method of analysis and interpretation of the data. The study was conducted to find out the effect of citric acid dressing on diabetic foot ulcer. Data was collected from 16 samples. The findings were tabulated analyzed and interpreted in this chapter. The data was analyzed using descriptive and inferential statistics.

### **SECTION –I**

#### **4.1. ANALYSIS OF DEMOGRAPHIC AND PHYSIOLOGIC VARIABLES**

The demographic variables of patients were collected in terms of age and gender and duration of history smoking. The physiological variables were duration of diabetes, history of foot ulcer, fasting blood sugar level, hemoglobin level, history of medication, exercise and diet.

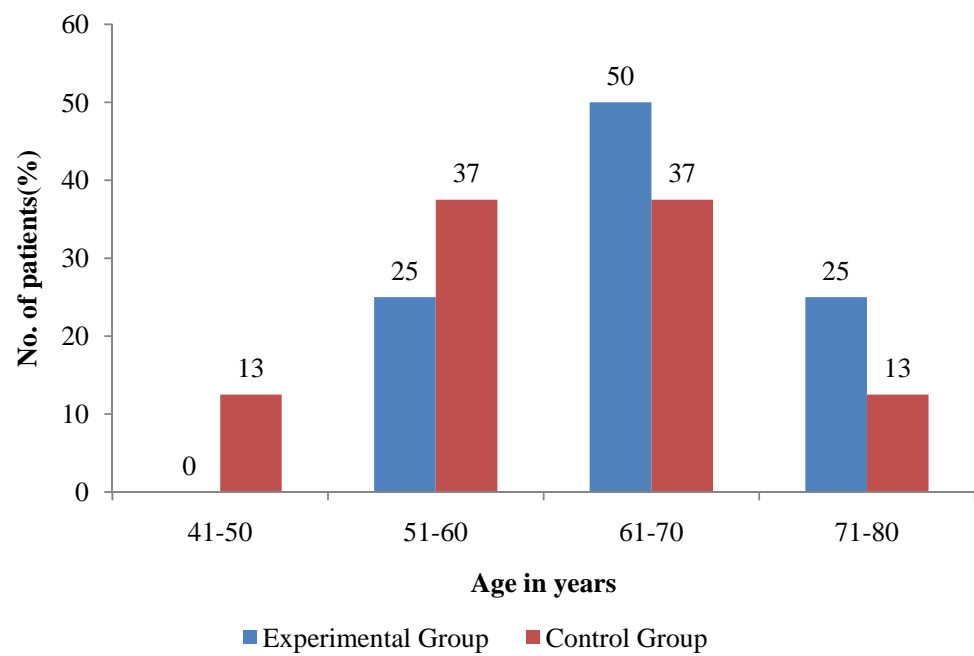
**TABLE 4.1**  
**DISTRIBUTION OF DEMOGRAPHIC VARIABLES**  
**AMONG DIABETIC PATIENTS**

(N=16)

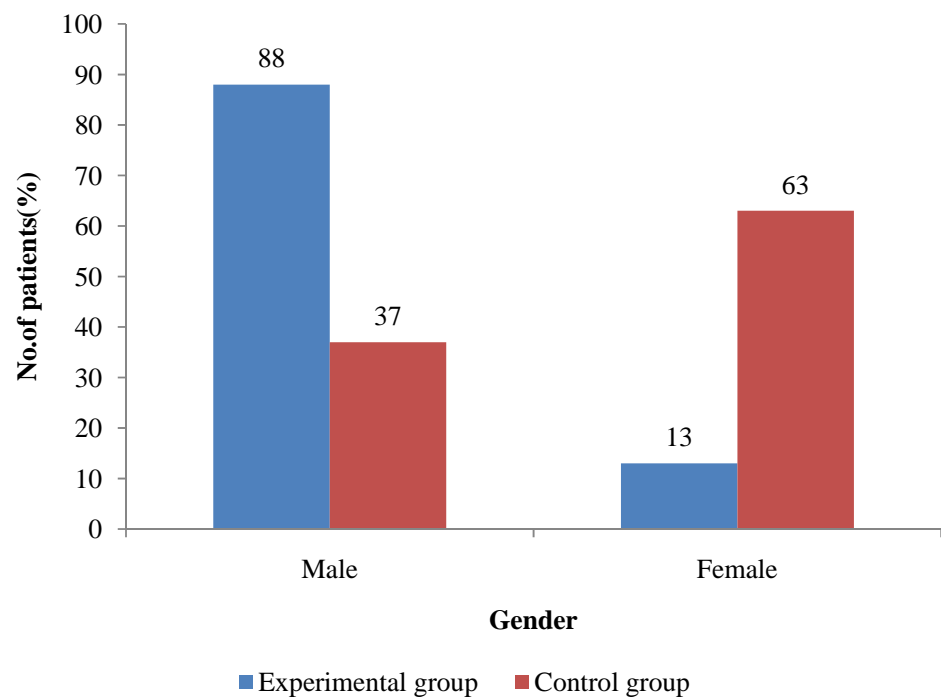
Demographic variables	Experimental group		Control group	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
<b>Age in years</b>				
41-50	-	-	1	13
51-60	2	25	3	37
61-70	4	50	3	37
71-80	2	25	1	13
<b>Gender</b>				
Male	7	87	3	37
Female	1	13	5	63
<b>Duration of History of smoking (years)</b>				
Non smokers	4	50	5	63
1-10	-	-	-	-
>10	4	50	3	37

Table 1.4 reveals the distribution of age, gender and history of smoking. In experimental group 50% of participants were between 61-70 years of age and in control group 37% of patients were between 51-60 years and 37% were between 61-70 years of age. In the case of gender, in experimental group 87% were male and 12% were female. In control group 37% were female and 63% were female. History of smoking in experimental group shows that 50% were non smokers and another 50% were smokers for more than 10 years. In control group 63% were non smokers and 37% were smokers for more than 10 years.

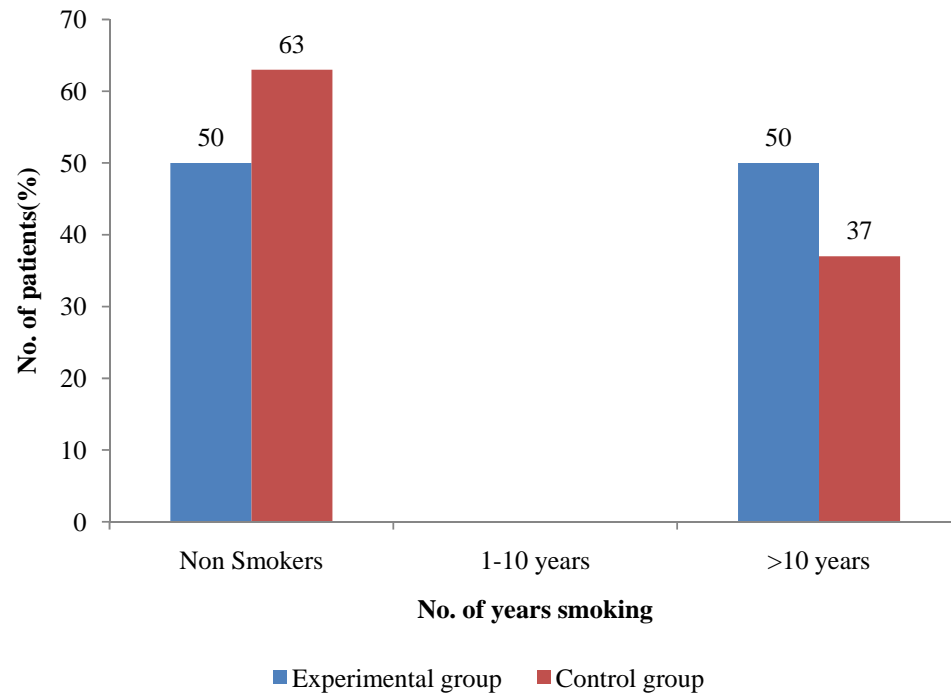
**FIG. 4.1**  
**AGE DISTRIBUTION OF DIABETIC PATIENTS**



**FIG. 4.2**  
**GENDER DISTRIBUTION OF DIABETIC PATIENTS**



**FIG. 4.3**  
**DISTRIBUTION ON DURATION OF HISTORY OF SMOKING**



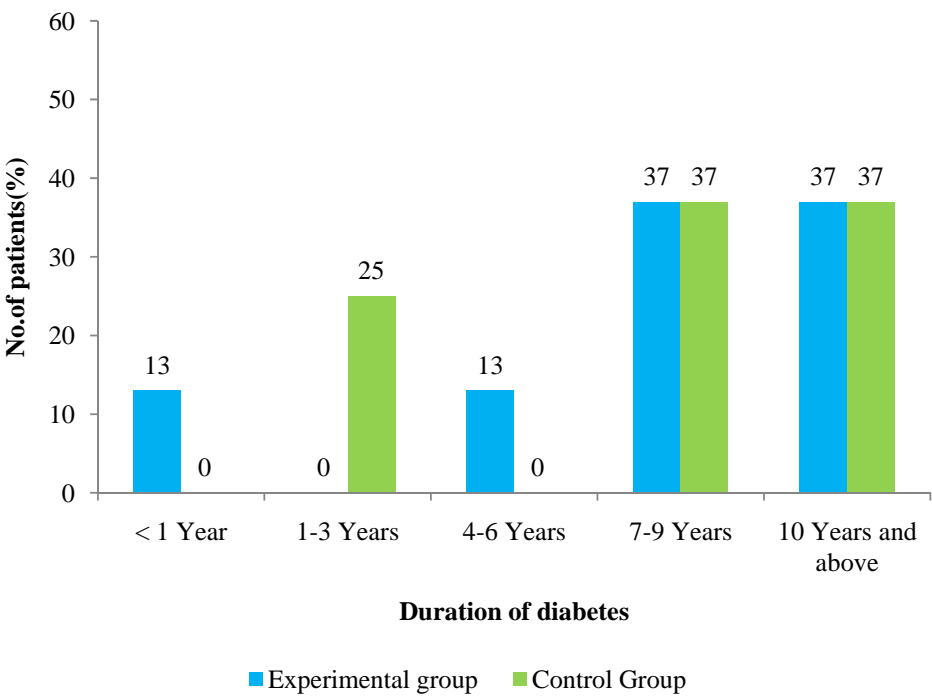
**TABLE 4.2**  
**DISTRIBUTION OF PHYSIOLOGIC VARIABLES AMONG DIABETIC**  
**PATIENTS**

(N=16)

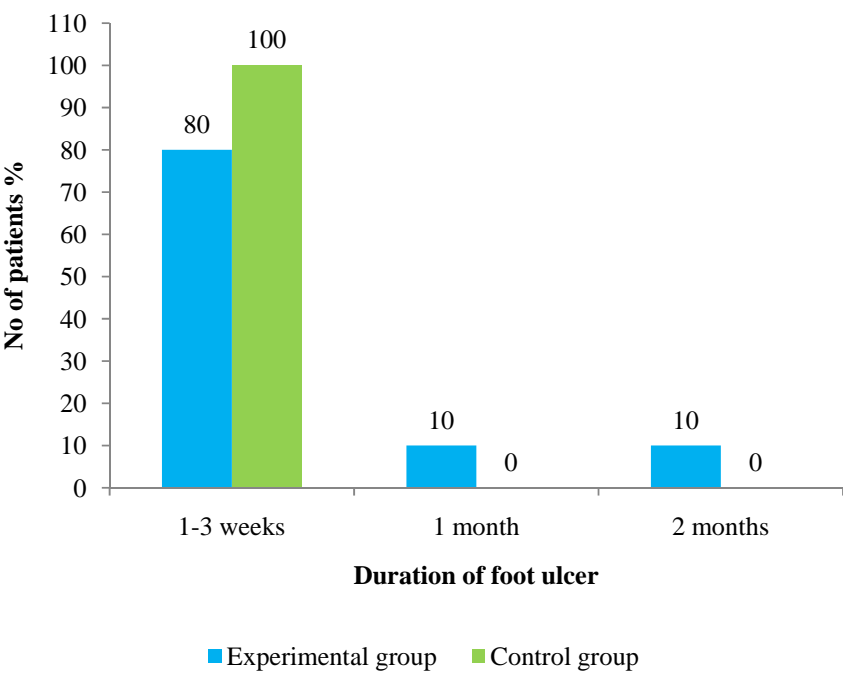
Physiologic variables	Experimental group		Control group	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
<b>Duration of diabetes (years)</b>				
<1	1	13	-	-
1 – 3	-	-	2	25
4 – 6	1	13	-	-
7 – 9	3	37	3	37
≥10	3	37	3	38
<b>Duration of History of food ulcer</b>				
<1 month	6	80	8	100
1 month	1	10	-	-
2 months	1	10	-	-
<b>Mean fasting blood sugar (mg/dl)</b>				
80 – 120	2	25	1	13
121 – 160	1	12	2	25
161 – 200	4	50	5	62
>200	1	13	-	-
<b>Hemoglobin level (g/dl)</b>				
90.0 – 10.0	2	25	2	25
10.1 – 11.0	5	63	3	38
11.1 – 12.0	1	12	2	25
>12.0	-	-	1	12

Table 4.2 shows the duration of diabetes mellitus both in experimental and control group, 37% of the patients had the history of 7-9 year and 37% had the history of more than 10 years. In the case of duration of diabetic foot ulcer, majority of patients had the history of less than 1 month that is 80% in experimental group and 100% in control group. The data regarding mean fasting blood sugar shows that majority of patients in both experimental and control group had the mean blood sugar ranging between 161-200 mg/dl that is 50% and 62% respectively. In the case of level of hemoglobin 63% of patients of experimental group had the value between 10.1-11.0 g/dl. In control group 38% had the value between 10.1-11.0 g/dl and 12% had above 12 g/dl.

**FIG. 4.4**  
**DISTRIBUTION ON DURATION OF DIABETES MELLITUS**

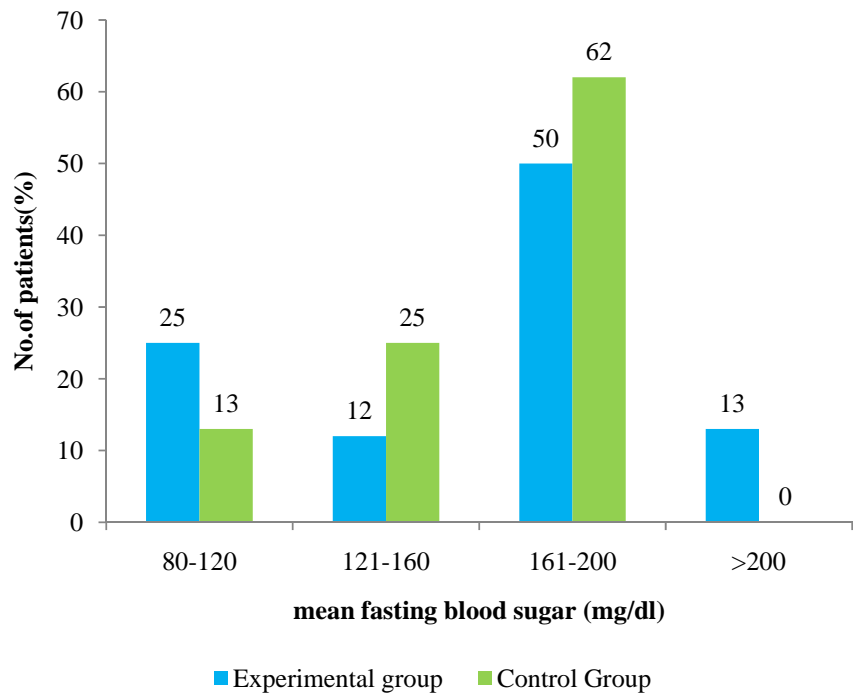


**FIG. 4.5**  
**DISTRIBUTION ON DURATION HISTORY OF FOOT ULCER**

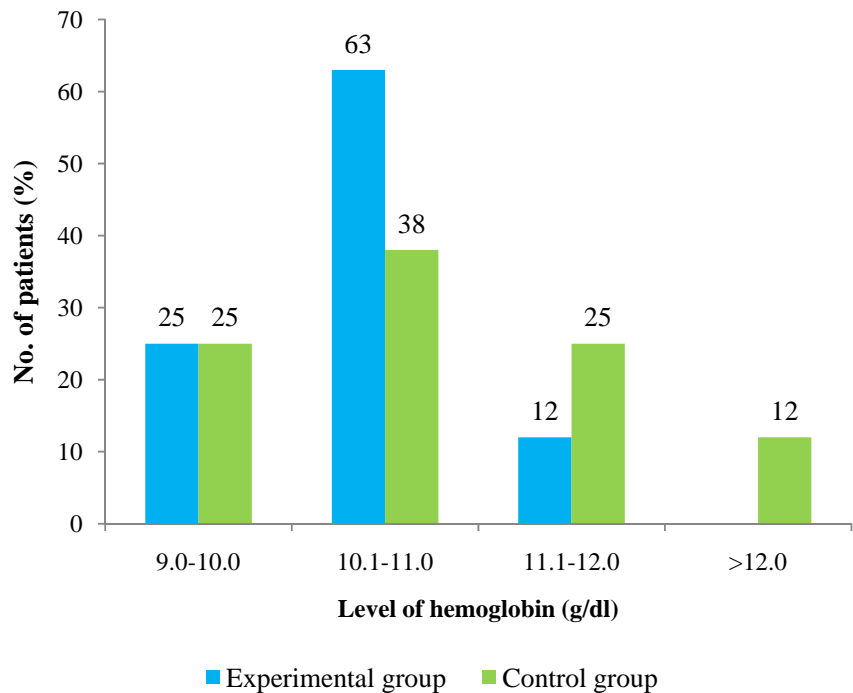




**FIG. 4.6**  
**DISTRIBUTION OF MEAN FASTING BLOOD SUGAR LEVEL**



**FIG. 4.7**  
**DISTRIBUTION ON LEVEL OF HEAMOGLOBIN**



#### **4.1.1. Distribution of History of Medication, Exercise and Diet Among diabetic Patients**

In experimental group and control group 75% of patients were on Insulin injection ( Inj. Human insulin was administered according to the blood sugar level as per physician order) and 25% of patients were on oral hypoglycemic agents (two patients were on Tab. Glyciphage 500mg bd and one patient was on Tab. Glimitide 1gm bd.). Among 16 samples 6 patients were on intravenous antibiotic Inj. Ceftriaxone 1 gm bd and 4 patients were on oral antibiotic Tab. Cefime 500mg bd and other 6 were not on any antibiotics. None of the patients had the habit of doing exercise. In the case of diet all patients were on diabetic diet, the usual daily menu includes wheat products two times a day and rice based food once in a day and one serving of fruits and vegetables. They consumed non vegetarian foods once or twice in a week and avoided sweet items in their diet.

## SECTION II

## 4.2. ANALYSIS ON INITIAL AND FINAL WOUND STATUS SCORES OF EXPERIMENTAL AND CONTROL GROUP

The wound status score of the diabetic wound before starting the treatment and the wound status score after the treatment of experimental and control group are presented in the following tables. To analyze the wound status score among the patients with foot ulcers before and after intervention ‘t’ test was used. This is to find the effect of citric acid dressing and the level of significance in experimental and control group.

**TABLE 4.3**  
**ANALYSIS OF INITIAL WOUND STATUS SCORES OF**  
**EXPERIMENTAL GROUP AND CONTROL GROUP**

(N= 16)

Wound status score	Mean	Mean percentage	Standard deviation	Mean difference	‘t’
Initial score (Exp. Group)	32.5	50	2.47	0.25	0.16
Initial Score (Control group)	32.25	49.61	9.79		

The calculated ‘t’ value 0.16 is lesser than the table value (1.761) which is not significant at 14 degrees of freedom at 0.05 level of significance. So it is proved that there is no significant difference in wound status among the experimental and control group before starting the treatment. Thus the hypothesis  $H_{01}$ , **“There is no significant difference in the wound status among experimental and control group before application of citric acid”** is accepted.

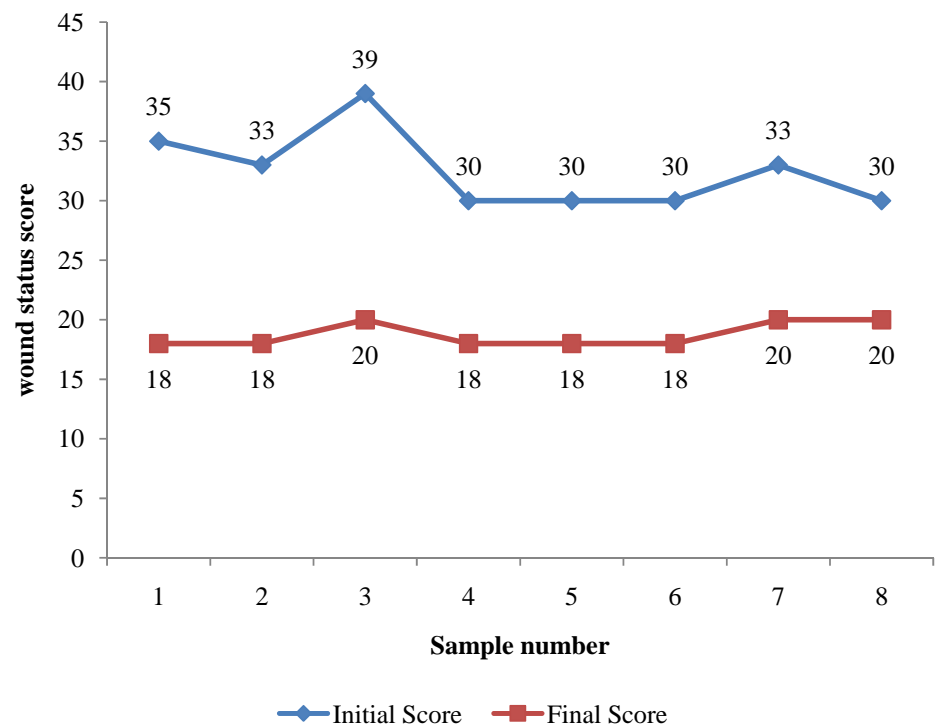
**TABLE 4.4**  
**INITIAL AND FINAL WOUND STATUS SCORES**  
**OF EXPERIMENTAL GROUP**

(N=16)

Sample Number	Initial score	Final score	Difference
1	35	18	17
2	33	18	15
3	39	20	19
4	30	18	12
5	30	18	12
6	30	18	12
7	33	20	13
8	30	20	10
			Mean= 13.75

Table 4.4 reveals the initial and final wound status score of the experimental and control group and the difference between them. The mean difference in the wound status score was 13.75.

**FIG. 4. 8**  
**INITIAL AND FINAL WOUND SCORE OF EXPERIMENTAL GROUP**



**TABLE 4.5**  
**ANALYSIS OF WOUND STATUS SCORE OF**  
**EXPERIMENTAL GROUP**

(N=8)

Wound status score	Mean	Mean percentage	Standard deviation	Mean difference	't'
Initial score	32.5	50	2.47	13.75	12.87*
Final Score	18.75	28.46	0.96		

\*Significance at the level of 0.05

The mean score of patients with diabetic foot ulcer in experimental group before starting the intervention was 32.5. And the final score decreased to 18.75 and the mean difference was 13.75 which shows that there is an improvement in wound status after citric acid dressing. And the calculated 't' value 12.87 is greater than the table value (1.897) at 7 degrees of freedom at 0.05 level of significance which indicates that significant improvement of the wound status after application of citric acid dressing among the patients of experimental group. Thus the hypothesis H<sub>2</sub>, **“There is a significant difference in wound status among experimental group before and after application of citric acid”** is accepted.

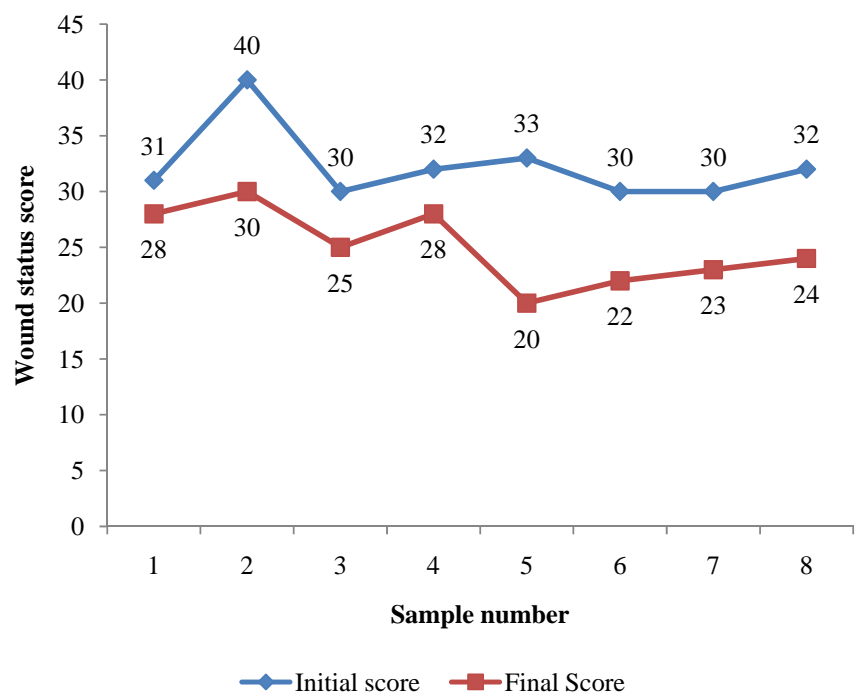
**TABLE 4.6**  
**INITIAL AND FINAL WOUND STATUS SCORES OF CONTROL GROUP**

(N=16)

Sample Number	Initial score	Final score	Difference
1	31	28	3
2	40	30	10
3	30	25	5
4	32	28	4
5	33	20	13
6	30	22	8
7	30	23	7
8	32	24	8
			Mean = 7.25

Table 4.6 reveals the initial and final wound status score of the control group and the difference between them. The mean score difference of wound status score was 7.25.

**FIG. 4.9**  
**INITIAL AND FINAL WOUND STATUS SCORE OF CONTROL GROUP**





**TABLE 4.7**  
**ANALYSIS OF WOUND STATUS SCORE OF CONTROL GROUP**

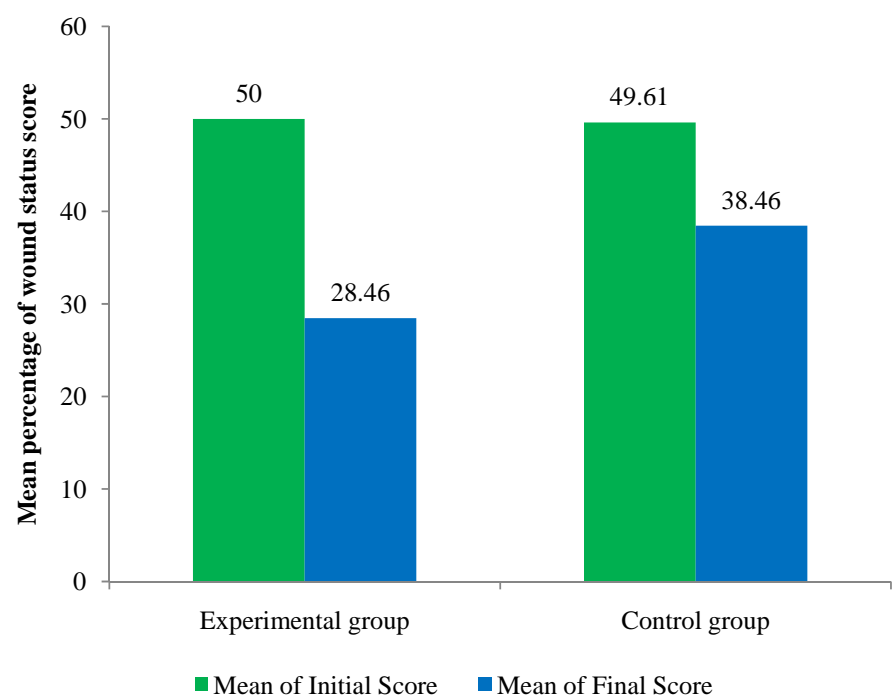
(N=8)

Wound status score	Mean	Mean percentage	Standard deviation	Mean difference	't'
Initial score	32.25	49.61	9.79	7.25	2.57*
Final Score	25	38.46	3.20		

\*Significant at the level of 0.05

Table 4.7 reveals the initial and final wound status score of patients of control group. The mean initial wound status score was 32.25 and the mean final score was 25 and the mean difference was 7.25 and the 't' value was 2.57. This calculated 't' value is greater than the table value (1.895) at 7 degrees of freedom at 0.05 level of significance. Even though the patients of control group is not exposed to citric acid dressing which shows a significant difference, this may be due to the influence of routine treatment. Thus the hypothesis H<sub>3</sub> “ **There is a significant difference in wound status among control group before and after routine wound dressing**” is accepted.

**FIG 4.10**  
**DISTRIBUTION OF MEAN WOUND STATUS SCORE OF**  
**EXPERIMENTAL AND CONTROL GROUP**



**TABLE 4.8**  
**ANALYSIS OF FINAL WOUND STATUS SCORE**  
**OF EXPERIMENTAL GROUP AND CONTROL GROUP**

(N= 16)

Wound status score	Mean	Mean percentage	Standard deviation	Mean difference	't'
Final Score (Exp. Group)	18.75	28.46	0.96		
Final Score (Control group)	25	38.46	3.20	6.75	9.92*

\*significance at the level of 0.05

The calculated 't' value was 9.92, which is greater than the table value (1.761) at 14 degrees of freedom at 0.05 level of significance. This proved that there is a significant difference between experimental group and control group after treatment. So citric acid dressing is effective in treating the diabetic foot ulcer. Thus the hypothesis  $H_4$ , **“There is a significant difference in wound status among experimental and control group after application of citric acid ”** is accepted.

### SECTION III

#### 4.3. CORRELATION BETWEEN SELECTED DEMOGRAPHIC AND PHYSIOLOGIC VARIABLES WITH FINAL WOUND STATUS SCORE OF CONTROL GROUP AND EXPERIMENTAL GROUP

Karl Pearson's coefficient of correlation was used to assess the relationship between the demographic and physiologic variables and final score of the wound.

**TABLE 4.8**  
**CORRELATION BETWEEN SELECTED DEMOGRAPHIC**  
**AND PHYSIOLOGIC VARIABLES WITH FINAL WOUND STATUS**  
**SCORE OF CONTROL GROUP**

(N=16)

Demographic & physiologic variables	'r'
Age	0.43
Duration of history of smoking	0.47
Fasting blood sugar level	0.66
Hemoglobin level	-0.58

Table 4.3 reveals the correlation between the demographic variables and physiologic variables with final wound status score of diabetic foot ulcer among patients of control group. There is a positive correlation( $r = 0.43$ ) exists between the age of the patients and final wound status score. This shows that when the age advances the wound status score also increases..

Duration history of smoking had also a positive correlation with final wound score, the value is  $r = 0.47$ . This confirms that smoking delays wound healing thus the wound status score also increases.

The level of fasting blood sugar has a positive correlation ( $r = 0.66$ ) with the final wound status score. This infers that when the fasting blood sugar level is higher it causes delay in wound healing thus the wound status score also increases.

The level of hemoglobin is inversely correlated which means that reduced level of hemoglobin levels increases the wound status score and the  $r$  value is  $-0.58$ .

**TABLE 4.9**  
**CORRELATION BETWEEN DEMOGRAPHIC AND**  
**PHYSIOLOGIC VARIABLES WITH FINAL WOUND**  
**STATUS SCORE OF EXPERIMENTAL GROUP**

(N=16)

Demographic & physiologic variables	'r'
Duration of history of smoking	0.46
Fasting blood sugar level	0.42
Hemoglobin level	0.6

Table 4.3 reveals the relationship or correlation between the demographic variables and physiologic variables with final wound status score of diabetic foot ulcer of patients in the experimental group.

The relation between the history of smoking is positively correlated with the final wound status score. This shows that smoking and longer the duration of foot ulcer will cause increased wound status score.

In the case of fasting blood sugar has a positive relation with the wound status score. This reveals that increased level of fasting blood sugar level also causes increased wound status score and delay the wound healing.

But in the case of level of hemoglobin, though there is a reduced level of hemoglobin among the samples (Table4.2) the wound status score also reduced, which shows the effectiveness of citric acid for the patients of experimental group.

## **RESULTS AND DISCUSSION**

The study was conducted among the patients with diabetic foot ulcer who were admitted in Sri Ramakrishna Hospital, Coimbatore, with the aim of identifying the effect of citric acid dressing on diabetic foot ulcer. Citric acid dressing was done for the experimental group and routine dressing was done for the control group. Demographic & physiologic variables were collected and the wound was assessed for both experimental and control group with the help of Bates Jensen Wound Assessment Tool. The results of both groups were compared, interpreted and discussed in this chapter.

### **5.1. FINDINGS RELATED TO DEMOGRAPHIC AND PHYSIOLOGIC**

#### **VARIABLES**

##### **5.1.1. Age**

In experimental group 50% of participants were between 61-70 years of age and in control group 37% of patients were between 51-60 years and 37% were between 61-70 years of age. The majority of patients in both the group were above 50 years.

Carrel & Nouy (1997) first time reported in the early 1920s the delay in wound healing is associated with ageing. It has also been reported that complications of wound healing such as wound dehiscence, are more common in older people.

A study was conducted by Desai (1997) among 225 older adults to explore the risk factors associated with wound healing, and reported that dermal changes associated with older people include reduction in skin thickness, elastic fiber, changes

to dermal ground substance and decreased vascularity and density. Age related cellular defects are shown by a decrease in the absolute number of cells, the number of hair follicles in growth phase, the diminished production of macro molecules which results in diminished production of collagen from the dermis are the major causes related to delay in wound healing among older adults.

### **5.1.2. Gender**

Among 16 patients 10 patients (63%) were male and 6 patients (37%) were female which reveals that majority of the samples were males.

A retrospective cohort study conducted by Taylor, Taylor & Smith, (2002) on 325 patients indicate that male gender was one of the predisposing factors to poor healing of venous ulcers.

A study conducted by Desiree & Tania (2006) determined wound healing rates in 18 elderly men by creating punch biopsy wounds and measuring wound size by planimetry on Day 7 post-wounding. The researchers then correlated healing among elderly men and women. Their results showed a significant wound repair delay in the healthy elderly men. And also the researchers conclude that elderly men heal more slowly than elderly women.

### **5.1.3. Duration of Diabetes Mellitus**

In control and experimental group 37% of patients had the history of diabetes mellitus between 7 to 9 years. Likewise 38% of patients of control group and 37% of patients in experimental group had the history of more than 10 years. Thus majority of the people had the disease for longer duration.



A study was conducted by Bennett (2004) on analysis of risk factors for diabetic foot ulceration; the result reveals that one of risk factors is long duration of history of diabetes mellitus. It has been shown that a positive relation exists between duration of diabetes and initial wound status score and final wound status score. i.e., as duration of diabetes mellitus increases wound status score increasing indicating a slower wound healing.

#### **5.1.4. History of Smoking**

In this study out of 16 samples 7 (43%) patients had the history of smoking more than 10 years. Just, Miller & Sandra (2002) explains that smoking delays wound healing and the reason for this is smoking causes vasoconstriction and lack of oxygen reaching to the skin cells, decreased collagen synthesis, and delayed growth of new blood vessels with in the wound.

According to a study conducted by Silverstein (1992) the documented effects of the toxic constituents of cigarette smoke--particularly nicotine, carbon monoxide, and hydrogen cyanide--suggest potential mechanisms by which smoking may undermine expeditious wound repair. Nicotine is a vasoconstrictor that reduces nutritional blood flow to the skin, resulting in tissue ischemia and impaired healing of injured tissue. Nicotine also increases platelet adhesiveness, raising the risk of thrombotic micro vascular occlusion and tissue ischemia. In addition, proliferation of red blood cells, fibroblasts, and macrophages is reduced by nicotine. Carbon monoxide diminishes oxygen transport and metabolism, whereas hydrogen cyanide inhibits the enzyme systems necessary for oxidative metabolism and oxygen transport

at the cellular level. Slower healing has been observed clinically in smokers with wounds resulting from trauma, disease, or surgical procedures.

#### **5.1.5. History of Foot Ulcer**

In experimental group 80% of patients had the duration of foot ulcer < 1 month where as all patients in control group had the history of < 1 month of foot ulcer.

David, Lynne, Ole & Jesse (2002) conducted a cohort study among > 3100 individuals with diabetic neuropathic foot ulcer. The researchers investigated the major factors that delays wound healing by providing them adequate treatment to the diabetic wound. The result showed that longer duration of wound is one of the factors associated with wound healing process by 20 week of care.

#### **5.1.6. Fasting blood sugar level**

In experimental group 50% of patients and in control group 62% of patient had the mean fasting blood sugar ranging from 161-200 mg/dl.

A study conducted by Martson (2006) shows that there is a high level of positive correlation exists between wound healing and hyperglycemia. The two serious consequences of elevated blood sugar levels are a reduction in the function of neutrophils as phagocytes and alteration in the deposition of collagen by fibroblasts with subsequent reduction in the wound strength.

An additional negative outcome of poorly managed diabetes and ongoing hyperglycemia is malnutrition. Because of the lack of insulin cells become starved for nutrients, and proteins and fat are used as energy sources, consequently the patient

becomes catabolic. Obviously the energy is required for the synthesis of new tissues, which is non supportive of healing.

#### **5.1.7. Level of Hemoglobin**

In experimental group 88% of patients and in control group 63% percentage of patients had the hemoglobin level below 11.0 g/dl. It has been shown that hemoglobin levels increases wound status score decreases, thus there was an inverse relation between them. Tissue perfusion and oxygenation are essential to the tissue repair. Sussman & Jensen (2007) stated that Hemoglobin level less than 12 g/dl in an important risk factor for wound healing.

According to Jonsson, Jensen & Goodson (1991) Wound healing depends on oxygen availability to the wound environment and adequate blood flow to deliver oxygen and remove metabolic waste products from the injury site. Hypoxia, decreased oxygen in the tissue, usually results in impaired healing.

#### **5.1.8. History of Medication, Exercise and Diet**

In experimental group and control group 75% of patients were on Insulin injection ( Inj Human insulin was administered according to the blood sugar level as per physician order)and 25% of patients were on oral hypoglycemic agents(two patients were on Tab.Glyciphage 500mg bd and one patient was on Tab. Glimitide 1gm bd.). Among 16 samples 6 patients were on intravenous antibiotic Inj Ceftriaxone 1 gm bd and 4 patients were on oral antibiotic Tab. Cefime 500mg bd and other 6 were not on any antibiotics. None of the patients had the habit of doing exercise. In the case of diet all patients were on diabetic diet, the usual daily menu includes wheat products two times a day and rice based food once in a day and one

serving of fruits and vegetables. Non vegetarian foods once or twice in a week and avoided sweet items in their diet.

A study conducted by Koblik, Sieradzki, Sendur & Biernat (2001) shows that subcutaneous insulin injection improves the post ischemic skin blood flow in ulcerated feet and they had clinically proven that the time needed for healing is highly significant.

Apelqvist & Agardh (1992) investigated the association between the risk factors and outcome of diabetic foot ulcers and the result shows that there is significant association exists with glycemic control by diet with the number of days needed for the healing of foot ulcers.

### **5.3. ANALYSIS OF WOUND STATUS SCORES IN EXPERIMENTAL AND CONTROL GROUP.**

With regard to effect of citric acid dressing 16 patients with diabetic foot ulcer were randomly assigned to experimental and control group. Wound status was assessed with Bates Jensen Wound Assessment Tool both experimental and control group. Paired 't' test was used to prove the significance of citric acid dressing.

Table 4.3 shows the analysis of initial wound status score of experimental and control group. The mean difference of initial wound status score of experimental and control group was 0.25 and the calculated 't' value (0.16 ) is lesser than the table value (1.761) which is not significant at 14 degrees of freedom at 0.05 level of significance. So it is proved that there is no significant difference in wound status among the experimental and control group before starting the treatment. Thus the

hypothesis  $H_{01}$ , **“There is no significant difference in the wound status among experimental and control group before application of citric acid”** is accepted.

Table 4.5 shows the analysis of initial and final wound status score of experimental group. The mean score of patients with diabetic foot ulcer in experimental group before starting the intervention was 32.5. And the final score decreased to 18.75 and the mean difference was 13.75 which shows that there is an improvement in wound status after citric acid dressing. And the calculated ‘t’ value 12.87 is greater than the table value (1.897) at 7 degrees of freedom at 0.05 level of significance which indicates that significant improvement of the wound status after application of citric acid dressing among the patients of experimental group. Thus the hypothesis  $H_2$ , **“There is a significant difference in wound status among experimental group before and after application of citric acid”** is accepted.

Table 4.7 reveals the initial and final wound status score of patients of control group. The mean initial wound status score was 32.25 and the mean final score was 25 and the mean difference was 7.25 and the ‘t’ value was 2.57. This calculated ‘t’ value is greater than the table value (1.895) at 7 degrees of freedom at 0.05 level of significance. Even though the patients of control group is not exposed to citric acid dressing which shows a significant difference, this may be due to the influence of routine treatment. Thus the hypothesis  $H_3$  **“ There is a significant difference in wound status among control group before and after routine wound dressing”** is accepted.

When comparing the results of table 4.5 and 4.7 the mean difference before and after citric acid dressing of experimental group was 13.75 and the mean difference before and after routine wound dressing of control group was only 7.25.

This clearly depicts that application of citric acid has made an impact in healing of the wound of experimental group patients faster than the control group patients.

Table 4.8 shows the analysis of final scores of experimental and control group in which the calculated 't' value was 9.92, which is greater than the table value (1.761) at 14 degrees of freedom at 0.05 level of significance. This proved that there is a significant difference between experimental group and control group after treatment. So citric acid dressing is effective in treating the diabetic foot ulcer. Thus the hypothesis  $H_4$ , **“There is a significant difference in wound status among experimental and control group after application of citric acid ”** is accepted. Hence the result shows that there is a significant improvement in the wound healing after application of citric acid dressing for the diabetic foot ulcers when compare to the control group. Thus the above findings are consistent with the studies conducted by Nagoba (2008), Gandhi (2010), and Wadher, Kore, Gomashe & Ingle (2008) who investigated that citric acid as the sole microbial agent in treating the wounds and also proves that it is a simple, affordable and effective approach in treating the foot ulcers.

#### **5.4. CORRELATION BETWEEN SELECTED DEMOGRAPHIC AND PHYSIOLOGIC VARIABLES WITH FINAL WOUND STATUS SCORE OF CONTROL GROUP AND EXPERIMENTAL GROUP**

Correlation between the selected demographic and physiologic variables with the final wound status score of both control and experimental group were analyzed by Karl Pearson's coefficient of correlation. The results were tabulated in Table 4.8 and 4.9.

The results shows that there is positive relation exists between the age and final wound status score of control group ( $r = 0.43$ ). When the age advances the

wound status score also increases which indicates that there is a delay in wound healing. But in the case of experimental group and a negative correlation exists with final wound status score( $r = -0.24$ ). A clinical review conducted by Minimas (2007) suggests that though several factors are associated with ageing that delayed the wound healing the researchers found that controlling of associated factors such as infection and appropriate wound care techniques promotes normal wound healing among older adults. Even in the present study the researcher found that wound healing process was not affected by the ageing since citric acid dressing is an appropriate agent for wound healing and also it controls the infection.

The relationship between the history of smoking and final wound status score is positive for both the control and experimental group, and the 'r' value is 0.47 and 0.46 respectively. This result reveals that smoking delays the wound healing process.

The correlation between the level of fasting blood sugar and the final wound status score shows a positive correlation among the patients of both control and experimental group ( $r = 0.66$  and  $0.42$ ). Glycemic control is one of the major factors in the wound healing process. The result shows when the mean fasting blood sugar level influenced the wound status score. That is the wound status score is increased when the fasting blood sugar level increased.

In control group the relation between the hemoglobin level is inversely correlated ( $-0.58$ ) indicates that when the hemoglobin level decreased the wound status score also increased indicative of poor wound healing. But in the case of experimental group it is positively correlated ( $r = 0.6$ ) which shows the effectiveness

of citric acid dressing among the patients of experimental group even with the reduced level of hemoglobin. This finding was consistent with the study conducted by Mandai, Equichi, Tanaka, Sai & Nosaka (2001) which shows that Wound healing is influenced by tissue oxygen tension and blood perfusion, but not due to moderate anemia or hemodilution or reduced level of hemoglobin. Thus it is proven that citric acid dressing improves the tissue oxygenation there by wound healing.



## SUMMARY AND CONCLUSION

This chapter summarizes the major findings, limitations, implications in the field of nursing education, nursing practice, nursing research and recommendation.

The study is to identify the effect of application of citric acid on diabetic foot ulcer among diabetic patients. The study design was one group pre test and post test with control group. The data was collected for a period of thirty days at Sri Ramakrishna Hospital, Coimbatore. The study was conducted on 16 patients, 8 each were randomly assigned to experimental and control group. Citric acid dressing was done for the experimental group and routine dressing was done for patients of control group. The wound status was assessed by Bates Jensen Wound Assessment Tool.

### 6.1. MAJOR FINDINGS OF THE STUDY

1. Citric acid dressing was found to be effective in treating the diabetic foot ulcer.
2. The healing of foot ulcer in experimental group was found to be faster when compared to the control group.
3. The correlation between the selected demographic and physiologic variables with final wound status score shows the following results:
  - (i) There was a positive correlation between duration of history of smoking, fasting blood sugar level and final wound status score in both experimental and control group which indicates that smoking and increased blood sugar level causes delay in wound healing process.
  - (ii) In control group there was a negative correlation between haemoglobin level and final wound status score indicating that reduced level of

haemoglobin causes delay in wound healing. In experimental group there is a positive correlation between the haemoglobin level and final wound status score which indicates that citric acid application enhances wound healing process even when the haemoglobin level is reduced. This infers that citric acid has got the property of tissue oxygenation.

## **6.2. LIMITATIONS OF THE STUDY**

1. The study was conducted on less number of subjects.
2. No comparison was done with specific topical agents used for wound dressing.

## **6.3. NURSING IMPLICATIONS**

### **6.3.1. Nursing Education**

People with diabetic foot ulcer receive various methods of treatment. To manage the symptoms effectively many are turning to alternative therapies like herbal medicines and various other topical agents. Among these therapies citric acid dressing is one of the alternative treatments. In the field of nursing education, topical application of citric acid dressing for diabetic wound is concerned with holistic care of patients. Thus, it is appropriate to incorporate alternative therapies like citric acid dressing into nursing curriculum.

### **6.3.2. Nursing Practice**

The nurse working in the surgical unit should be trained in implementing citric acid dressing as complementary therapy to bring out positive physical and psychological responses as an adjunctively to other pharmacological treatment to promote comfort and well being among the diabetic foot ulcer patients.

### **6.3.3. Nursing Research**

The nursing research need to focus more on the evidence based and holistic practice through understanding the various techniques that can bring about significant positive and psychological outcomes for patients with diabetic foot ulcer.

The nursing research intended to offer up to date suggestions in implementing the alternative treatments like citric acid dressing application as one of the nursing intervention for the foot ulcer which is an affordable and effective way of treating foot ulcers.

### **6.4. RECOMMENDATIONS**

1. Local application of citric acid dressing can be used as a routine intervention among patients with diabetic wound in hospitals.
2. An extensive experimental study can be conducted for larger number of samples in the health care settings.
3. Further research can be conducted with the help of other wound assessment scale.
4. A study can be conducted to find out effectiveness of citric acid dressing in the healing of burns wound.
5. A comparative study can be conducted with other products used for wound dressing.

### **6.5. CONCLUSION**

Diabetic foot infections are the major cause of morbidity. Inappropriate treatment and infections is the common sequel of diabetic foot ulceration that leads to delayed wound healing. Diabetic foot ulcers at its later stages highly affect the

persons' quality of life and image. Citric acid is a product which contains the healing properties and anti microbial properties and it is effective in the successful management of foot ulcers in an affordable and simple way.

## References

- Aggarwal, K. (2004). Foot Complications in Diabetes. *Asian Journal of Diabetology*, 3(3), 22-23.
- Allen, V. (2008). Citric Acid Treatment for Diabetic Foot Ulcer. *Journal of Burns And Wound* , 3(1), 45-46.
- Apelqvist, J., & Agardh, C. (1992). The Association Between Clinical Risk Factors and Outcome of Diabetic Foot Ulcers. *Diabetes Research and Clinical Practice*, 18(1), 43-45.
- Bansal, E., & Garg, A. (2008). Spectrum of Microbial Flora in Diabetic Foot Ulcer. *Diabetes Care*, 33(2), 24-25.
- Bates-Jensen, B., & MuNees, P. (2001). Toward an Intelligent Wound Assessment System. *Ostomy/Wound Management*, 41(7a), 80-87.
- Bennet, J. (2004). Asscocoated Risk Factors for Wound Healing among Diabetic Patients. *Diabetes Care*, 14(2), 24-28.
- Boulton, A., Vilekeite, L., & Ragnarson, T. (2009). The Global Burden of Diabetic Foot Disease. *Lancet*, 366, 1719-24.
- Boyoko, E., Ahroni, J., Smith, D., & Davignon, D. (1996). Increased Mortality Associated with Diabetic Foot Ulcer. *Diabetic Medicine : A Journal of the British Diabetic Association*, 13(11), 967-72.
- Carrel., & Nouy. (1997). Cicatrization of Wounds. *Journal of Expert Medical Sciences*, 34, 339-48.

- Chandalia, M. (2001). Relationship Between Generalised and Upper Body Obesity to Insulin Resistance in Asian Indian Men. *Journal of Clinical Endocrinology and Metabolism*, 84, 2329-35.
- Culleton, J. (1999). Preventing diabetic foot complications. Tight G... [Postgrad Med. 1999] - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from [http://www.ncbi.nlm.nih.gov/pubmed?term=diabetic%20foot%20education\\_Gulleton%20J.L.%20](http://www.ncbi.nlm.nih.gov/pubmed?term=diabetic%20foot%20education_Gulleton%20J.L.%20).
- David, M., Lynne, A., Ole, H., & Jesse, B. A. (2002). Diabetic Neuropathic Foot Ulcers. *Diabetes Care* . Retrieved December 11, 2011, from <http://care.diabetesjournals.org/content/25/10/1835.short>.
- Davidson, S., & Haslett, C. (2002). *Davidson's Principles and Practice of Medicine* (19<sup>th</sup> Ed.,). Edinburgh: Churchill Livingstone.
- Deresinki, S. (2008). Intections in Diabetic Patients; Strategies for Clinicians. *Infectious Disease Repots*, 1(1), 34-35.
- Desai, J. (1997). Ageing and wound healing in old age. *Journal of wound care*, 6(5), 237-9.
- Desiree, M. O., & Tania, T. J. (2006). Sex Hormones and Wound Healing: Androgens and Wound Healing. *Wounds*, 18(1), 8-18.
- Diabetes. A Major Health Care Issue. (2010, January 20). *The Hindu*, p. A2.

Dumville, J., & Deshpande, S. (2011). Foam Dressings for Healing Diabetic Foot Ulcer. *Cochrane Database System Review*, 7(9), 111.

Femiano, F., Rullo, R., & Lanza, a. (2010). A Comparison of Salivary Substitute Versus Citric Acid in Patients Complaining of Dry Mouth: A Clinical Randomized Controlled Study. *Journal of Oral Surgery and Medicine*, 10(12), 134-35.

Fujiwara, Y., Kishida, K., Terao, M., Takahara, M., Matsuhisa, M., & Funahashi, T. (2011). Beneficial Effects of Foot Care Nursing For Peopl... [J Adv Nurs. 2011] - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/21480962>.

Gandhi, R. (2010). Simple, Effective And Affordable Approach For The Trea... [Burns. 2010] – PubMed – NCBI. *National Center for Biotechnology Information*. Retrieved December 25, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/20554394>.

George, J. B. (1995). *Nursing Theories: the Base for Professional Nursing Practice* (4<sup>th</sup> Ed.,). Norwalk, Conn.: Appleton & Lange.

Gottrup, F., & Jorgenson, B. (2011). Maggot Debridement: an Alternative Method for debrid... (Eplasty. 2011) - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/21776326>

- Guptha, S., Sing, Z., Purty, A. J., Kar, M., & Maharajan, P. (2010). Diabetes Prevalance and Riskfactors in Rural area of Tamilnadu. *Diabetes Research and Clinical Practice*, 33, 180-83.
- Gutyon, A. (2009). Effect of Citric Acid Dressing against Sulfadiazine Dressing for Burn Injury. *Journal of Hospital Infection*, 64(6), 245-46.
- Hamilton, G., Differding, P., & Van, J. (2005). Lyophilized Plasme with Accorbic Acid and Citric Acid Decreases Inflammation in Hemorrhagic Shock. *Journal of Wound Care*, 12(10), 144-45.
- Harris, C., Bates-Jensen, B., Parslow, N., Raizman, R., & Singh, M. (2009). The Batesâ€™ Jensen Wound Assessment Tool (BWAT): Development of a Pictorial Guide for Training Nurses. *Wound Care Canada*, 7(2), 33-38.
- Hess, C. T. (2005). *Wound care* (5<sup>th</sup> Ed.). Philadelphia: Lippincott Williams & Wilkins.
- Hofman, A., & Willie, J. (1994). Pressure Sores and Pressure Decreasing Mattress: Controlled Clinical Trial . *Lancet*, 343(8897), 568-71.
- Jonsson, K., Jenson, J., & Goodson, W. (1991). Tissue Oxygenation, Anemia, and Perfusion in Relation to Wound Healing in Surgical Patients. *National Center for Biotechnology Information*. Retrieved December 24, 2011, from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1358617/>
- Just, S., Miller, K., & Sandra, F. (2002). Smoking and Wound Healing. *Wounds*, 17(1), 123-25.



- Kim, H. S., & Kollak, I. (2006). *Nursing Theories: Conceptual & Philosophical Foundations* (2<sup>nd</sup> Ed.,). New York, NY: Springer Pub. Co.
- Koblik, T., Sieradzki, J., Sendur, R., & Biernat, J. (2001). The Effect of Insulin and Sulodexide (Vessel Due F) on Diabetic Foot Syndrome: Pilot Study in Elderly Patients. *Journal of Diabetes Complications*, 15(2), 69-74.
- Levin, M. (2002). Management of the Diabetic Foot; Preventing Amputation. *South Medical Journal*, 22, 10-20.
- Lewis, S. M., Heitkemper, M. M., & Dirksen, S. R. (2007). *Medical Surgical Nursing: Assessment and Management of Clinical Problems* (7<sup>th</sup> Ed.,). St. Louis: Mosby.
- Lickman., Fontento, J., & Rahnema, R. (1995). Citric Acid and Hyaluronic Acid Based Gel Dressing for Diabetic Foot Ulcer . *Diabetes Care*, 35(4), 23-24.
- Mandai, R., Equchi, Y., Tanaka, M., Sai, Y., & Nosaka, S. (2001). Effects of Profound Hemodilution on Small-Intesti... (J Surg Res. 2001) - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved December 24, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/11421611>
- Mani, R., Yadre, S., & Edmonds, M. (2011). Prevalence of Deep Venous Incompeten... (Int J Low Extrem Wounds. 2011) - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/21693442>

- Martson. (2006). Slow Wound Healing Due to Elevated Blood Sugar. *Nutrition Supplements News*. Retrieved December 11, 2011, from <http://www.nutralegacy.com/blog/general-healthcare/slow-wound-healing-due-to-elevated-blood-sugar/>.
- Minimas, D. (2007). Ageing and its Influence on Wound Healing. *Wounds UK*, 3(1), 43-45.
- Mohan, V. (2010, May 22). Diabetes in Tamilnadu. *The Hindu*, p. A4.
- Mohan, V., Sharp, R., cloke, H., & Burrin, J. (2007). Immunoreactive Insulin Responses to Aglucose load in Asian Indian and European Diabetes Patients and Control Subjects. *Diabetologia*, 29, 235.
- Nagoba, B. (2008). A Simple and Effective Approach for the treatm... [J Hosp Infect. 2008] - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved December 25, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/18485531>
- Nagoba, B. (2010). Citric Acid Treatment of Necrotizing Fasciitis: a Report of Two Cases - Nagoba - 2010 - International Wound Journal - Wiley Online Library. *Wiley Online Library*. Retrieved December 25, 2011, from <http://onlinelibrary.wiley.com/doi/10.1111/j.1742-81X.2010.00721.x/abstract>.
- Nagoba, B. (2007). Microbiological, Histopathological and Clinical Changes in Chronic Infected Wounds After Citric Acid Treatment. *Journal of Medical Microbiology*. Retrieved December 25, 2011, from <http://jmm.sgmjournals.org/content/57/5/681.full>.

- Nain, P., Uppal, S., Bajaj, K., & Garg, S. (2011). Role of Negative Pressure and Wound Therapy in Healing of Diabetic Foot Ulcers. *Journal of Surgical Technique and Case Report*, 3(1), 17-22.
- Nather, A. (2010). Effectiveness of Vacuum-Assisted Clos... [Ann Acad Med Singapore. 2010] - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/20535423>
- Ormerod, A., & Shah, A. (2008). An Observational Prospective Study of Topical Citric Acid for Killing Methicillin-resistant Staphylococcus aureus (MRSA) in Contaminated Wounds. *Journal of wound care*, 5(10), 220-22.
- Pinzur, J. (2005). Health related Quality of Life; Cognitive Function and Depression in Diabetic Patients with Foot Ulcer or Amputation. *Diabetes Care*, 12(6), 144-145.
- Polit, D. F., & Beck, C. T. (2008). *Nursing Research: Generating and Assessing Evidence for Nursing Practice* (8<sup>th</sup> Ed.). Philadelphia: Wolters Kluwer Health/lippincott Williams & Wilkins.
- Position Statement - Type 2 Diabetes in Young People | International Diabetes Federation. (2010). *International Diabetes Federation*. Retrieved November 26, 2011, from <http://www.idf.org/position-statement-type-2-diabetes-young-people>.

- Potter, P. A., & Perry, A. G. (2009). *Fundamentals of Nursing* (7th ed.). St. Louis, Mo.: Mosby.
- Ramachandran, A., Vishwanathan, V., & Haffner, S. (1997). Risk of Non Insulin Dependent Diabetes Melitus Conferred by Obesity and Central Adiposity in Differet Ethnic Group: A Comparative Analysis between Asian Indians, Mexican Americans & Whites. *Diabetes Research and Clinical Practice*, 36, 121-5.
- Renvert, S., Dahlen, G., & Snyder, B. (1997). Clinical and Microbiological Effects of Subgingival Antimicrobial Irrigation With Citric Acid as Evaluatedb an Enzyme Immunoassay and Culture Analysis. *Journal of Periodontal Diseases*, 68(4), 346-52.
- Sarah, W., Gojka, R., Andrews, G., Richard, S., & Hilary, K. (2009). Global Prevalance of Diabetes; Estimates for the year 2010 and Projections for 2030. *Diabetes Care*, 27(5), 1047-1053.
- Shankhadar, D. (2009). Foot Care Needs Improvisation. *Journal of Wound Care*, 2(1), 122-23.
- Silverstein. (1992). Smoking and Wound Healing. (Am J Med.) PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved December 11, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/1323208>
- Sing, N., Amstrong, D., & Lipsky, B. (2005). Preventing Foot Ulcer in Patients with Diabetes. *Journal of American Medical Association*, 293(2), 217-228.

- Sriwijitkamol, A., Mounngern, Y., & Vannaseang, S. (n.d.). Assessment and prevalences of diabetic comp... (J Med Assoc Thai. 2011) - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved November 30, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/21721443>
- Sussman, C., & Jensen, B. M. (2007). *Wound Care: a Collaborative Practice Manual* (3<sup>rd</sup> Ed.,). Philadelphia, Pa.: Lippincott Williams & Wilkins.
- Taylor, C. (2010). *Fundamentals of Nursing: the Art and Science of Nursing Care* (7<sup>th</sup> Ed.,). Philadelphia: Lippincott Williams & Wilkins.
- Taylor, R., Taylor, A., & Smith, J. (2002). Using an artificial Neural Network to Predict Healing Times and Risk Factors for Venous Leg Ulcers. *Journal of Wound Care*, 11(3), 101-105.
- Tiaka, E., Papanas, N., & Manolakis, A. (2008). The Role of Hyperbaric Oxygen in the Treatment of Diabetic Foot Ulcers.. *Angiology*, 8, 21-22.
- Van, D. B., Halkes, S., Ufford, H. V., & Hoekstra, M. (2003). A Novel Formulation of Metal Ions and Citric Acid Reduces Reactive Oxygen Species *in vitro*. *Journal of wound care*, 12(10), 413-8.
- Vinik, A. (1999). *The CADRE Handbook of Diabetes Management* (12<sup>th</sup> Ed.,). USA: Mosby.
- Vishvanathan, V., & Kumpatala, S. (2011). Pattern and Causes of Amputation in Diabetic Patients - A Multicentric Study from India. *Journal of Association of Physicians India*, 59, 148-51.

Wadher, B., Kore, A., Gomashe, G., & Ingle, A. (2008). A Simple and Effective Approach for the Treatment of Chronic Wound Infections Caused by Multiple Antibiotic Resistant *Escherichia Coli*. *Journal of Wound Care*, 70(4), 385-86.

Weller, R. (2006). The Effects of Topical Treatment with Acidified... (Nitric Oxide. 2006) - PubMed - NCBI. *National Center for Biotechnology Information*. Retrieved December 25, 2011, from <http://www.ncbi.nlm.nih.gov/pubmed/16731016>

Zazgornik, J. (2011). Citric Acid Inhibits Growth of *Helicobacter Pylori In Vitro*: A New Strategy for Eradication. *Journal of Wound Care*, 123(1-2), 38-40.

Zubair, M., Malik, A., & Ahmad, J. (2011). Incidence, Risk Factors for Amputation Among Patients with Diabetic Foot Ulcer in a North Indian Tertiary Care Hospital. *Foot (Edinb)*, 2, 132-34.